

1 **510(k) Third Party Review Program**
2 **Draft Guidance for Industry,**
3 **Food and Drug Administration Staff,**
4 **and Third Party**
5 **Review Organizations**

6
7 ***DRAFT GUIDANCE***

8 **This draft guidance document is being distributed for comment purposes**
9 **only.**

10
11 **Document issued on: September 14, 2018**

12
13 You should submit comments and suggestions regarding this draft document within 90 days of
14 publication in the *Federal Register* of the notice announcing the availability of the draft guidance.
15 Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the
16 Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm.
17 1061, Rockville, MD 20852. Identify all comments with the docket number listed in the notice of
18 availability that publishes in the *Federal Register*.

19
20 For questions about this document, contact the Third Party Review Program at
21 3P510K@fda.hhs.gov.

22
23 **This guidance is a reissuance of the draft guidance titled “510(k) Third Party**
24 **Review Program – Draft Guidance for Industry, Food and Drug**
25 **Administration Staff, and Third Party Review Organizations” issued on**
26 **September 12, 2016.**

27
28 **When final, this guidance will supersede “Implementation of Third Party**
29 **Programs Under the FDA Modernization Act of 1997; Final Guidance for**
30 **Staff, Industry, and Third Parties” issued on February 2, 2001, and**
31 **“Guidance for Third Parties and FDA Staff; Third Party Review of**
32 **Premarket Notifications” issued on September 28, 2004.**



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

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95 **Draft Guidance for Industry,**
96 **Food and Drug Administration Staff,**
97 **and Third Party Review Organizations**
98

99 *This draft guidance, when finalized, will represent the current thinking of the Food and Drug*
100 *Administration (FDA or Agency) on this topic. It does not establish any rights for any person*
101 *and is not binding on FDA or the public. You can use an alternative approach if it satisfies*
102 *the requirements of the applicable statutes and regulations. To discuss an alternative*
103 *approach, contact the FDA staff or Office responsible for this guidance as listed on the title*
104 *page.*

106 **I. Introduction**
107

108 The 510(k) Third Party (3P) Review Program (formally known as the Accredited Persons (AP)
109 Program) is authorized under section 523 of the Federal Food, Drug, and Cosmetic (FD&C)
110 Act.¹ Under this authority, FDA recognizes third parties to review premarket notification
111 (510(k)) submissions and recommend the initial classification of certain devices. FDA’s
112 implementation of section 523 establishes a process for recognition of qualified third parties to
113 conduct the initial review of 510(k) submissions for certain low-to-moderate risk devices eligible
114 for review under the 3P Review Program.² This guidance document also reflects amendments
115 made to section 523 by the FDA Reauthorization Act of 2017 (FDARA),³ which directed FDA
116 to issue draft guidance⁴ on the factors that will be used in determining whether a class I or class
117 II device type, or subset of such device types, is eligible for review by an accredited person.
118

¹ Section 523 of the FD&C Act uses the terms “accredited persons,” “accredit,” “accredited,” “accreditation,” “reaccredit,” “reaccredited,” and “reaccreditation.” The guidance does not use those statutory terms but rather defines such terms as “recognition,” and “rerecognition” as synonymous terms. These alternative terms are used in this guidance to harmonize the terms used by FDA and in the FD&C Act with those in the International Medical Device Regulators Forum (IMDRF) and Medical Device Single Audit Program (MDSAP) documents and are defined in Section IV of this guidance.

² Currently, the Center for Biologics Evaluation and Research does not regulate devices of the types subject to this guidance.

³ Pub. L. 115-52.

⁴ See section 523(a)(3)(B)(i).

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119 For the current edition of the FDA-recognized standards referenced in this document, see the
120 FDA Recognized Consensus Standards Database.⁵

121

122 The objectives of this draft guidance are:

123

- 124 1. To describe the factors FDA will use in determining device type eligibility for review by
125 3P Review Organizations
- 126 2. To outline FDA’s process for the recognition, rerecognition, suspension and withdrawal
127 of recognition for 3P Review Organizations
- 128 3. To ensure consistent quality of work among 3P Review Organizations through the
129 Medical Device User Fee Amendments (MDUFA) IV commitments authorized under
130 FDARA.⁶

131

132 When finalized, this guidance will supersede FDA’s guidance documents titled “Guidance for
133 Third Parties and FDA Staff; Third Party Review of Premarket Notifications” issued on
134 September 28, 2004⁷ and “Implementation of Third Party Programs Under the FDA
135 Modernization Act of 1997; Final Guidance for Staff, Industry and Third Parties” issued on
136 February 2, 2001⁸.

137

138 FDA's guidance documents, including this draft guidance, do not establish legally enforceable
139 responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should
140 be viewed only as recommendations, unless specific regulatory or statutory requirements are
141 cited. The use of the word *should* in Agency guidance means that something is suggested or
142 recommended, but not required.

143 **II. Background**

144 **A. Basis for 3P Review Program**

145

146 On August 1, 1996, FDA launched a voluntary third party 510(k) review pilot program for
147 selected medical devices. Under this pilot program, all class I devices that were not 510(k)
148 exempt at that time, and 30 class II devices were eligible for 3P review.

149

150 On November 21, 1997, the Food and Drug Administration Modernization Act (FDAMA) was
151 signed into law. Section 210 of FDAMA⁹ codified and expanded the pilot program by
152 establishing section 523 of the FD&C Act.

⁵ Available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ Pub L. 115-52.

⁷The third party guidance document issued in 2004 is available at
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082191.htm>

⁸The third party guidance document issued in 2001 is available at
<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094459.pdf>

⁹ Pub. L. 105-115

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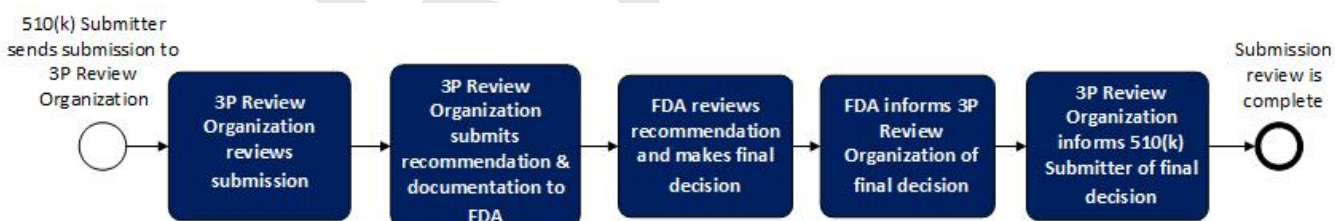
153
154 On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA)¹⁰ was
155 signed into law and required FDA to establish and publish criteria to accredit, reaccredit, and
156 deny reaccreditation of 3P Review Organizations that perform 510(k) reviews of eligible
157 devices.

158
159 On August 18, 2017, FDARA¹¹ was signed into law and required FDA to issue draft guidance on
160 the factors FDA will use in determining whether a class I or class II device type, or subset of
161 such device types, is eligible for review by 3P Review Organizations, including the risk of the
162 device type and whether the device type is permanently implantable, life sustaining, or life
163 supporting, and whether there is a detailed public health justification for permitting the review by
164 an accredited person of such device type. This guidance also addresses several MDUFA IV
165 commitments by including an early interaction consult policy and clarifying criteria for
166 rerecognition of 3P Review Organizations and the suspension or withdrawal of recognition.¹²
167

168 B. General Overview of 3P Review Program

169
170 The 3P Review Program is intended to enable FDA to focus its internal scientific review
171 resources on higher-risk and complex devices, while maintaining a high degree of confidence in
172 the review of low-to-moderate risk and less complex devices by 3P Review Organizations, and
173 to provide manufacturers of eligible devices a voluntary alternative review process that may
174 yield more rapid decisions on 510(k)s than from FDA. Figure 1 below provides a schematic
175 overview of the 3P Review Program.¹³
176

177 **Figure 1 – A General Overview of the 3P Review Program**
178



179
180
181 Under the 3P Review Program, 3P Review Organizations review a 510(k) submission and then
182 forward their review, the 510(k) submission, and a recommendation (e.g., substantially
183 equivalent (SE) or not substantially equivalent (NSE)) to FDA. FDA reviews the 3P Review

¹⁰ Pub. L. 112-144.

¹¹ Pub. L. 115-52.

¹² Through the MDUFA IV Commitment Letter, FDA commits to improving the 3P Review Program with a goal of eliminating routine re-review by FDA of 3P reviews:

<https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf>

¹³ Figure 1 uses IEC/IEC 19510: Information technology – Object Management Group Business Process Model and Notation (2013)

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184 Organization’s memo and recommendation and makes a final decision on the submission.
185 Section 523(a)(2) of the FD&C Act requires FDA to make a determination with respect to the
186 initial classification within 30 calendar days¹⁴ after receiving a recommendation from a 3P
187 Review Organization.

188
189 FDA recognizes 3P Review Organizations¹⁵ to review 510(k)s for certain device types eligible
190 for the 3P Review Program.¹⁶

191
192 Participation by 510(k) Submitters in the 3P Review Program is entirely voluntary.
193 Manufacturers who do not wish to use a 3P Review Organization may submit their 510(k)s
194 directly to the FDA for review, through either the Traditional, Special or Abbreviated Programs,
195 as appropriate.^{17,18}

196
197 As described in this draft guidance, the 3P Review Program includes features designed to ensure
198 a high level of quality in the review of 510(k)s by a 3P Review Organization and to minimize
199 risks to public health. A 3P Review Organization must be recognized by FDA under section
200 523(b) of the FD&C Act to be eligible to participate in the 3P Review Program. In evaluating a
201 3P Review Organization for recognition or rerecognition, FDA will consider the application, as
202 outlined in Section VIII of this guidance, provided by a 3P Review Organization. In addition,
203 FDA may consider past premarket review performance of the 3P Review Organization as
204 described in Section VIII.B.¹⁹

III. Scope

205
206
207 This draft guidance outlines FDA’s current thinking on key aspects of the 3P Review Program,
208 including:

- 209 1. FDA’s expectations for 3P Review Organization reviews of 510(k) submissions,
210 including new policy for early interaction consults (see Section VI)
- 211 2. New factors used to establish device type eligibility in the 3P Review Program (see
212 Section V)
- 213 3. Requirements and recommendations for recognition and rerecognition of 3P Review
214 Organizations under the 3P Review Program (see Section VII)

¹⁴ FDA uses calendar days when measuring on-time performance of user-fee supported premarket medical device submission reviews. See, “MDUFA Performance Goals and Procedures, Fiscal Years 2018 through 2022” at <https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf> for more information.

¹⁵ For a current list of recognized 3P Review Organizations under the 3P Review Program, please visit FDA’s website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/Accredit.cfm>.

¹⁶ For a current list of eligible devices for 3P review under the 3P Review Program, please visit FDA’s website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm>.

¹⁷ The guidance document describing the 510(k) Program is available on FDA’s website at <https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf>

¹⁸ The guidance document describing the 510(k) paradigm is available on FDA’s website at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf>

¹⁹ See section 523(b)(2) and section 523(b)(3)

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- 215 4. Content and format of a 3P Review Organization’s application for initial recognition and
216 rerecognition (see Section VIII)
217 5. Process for suspension or withdrawal of recognition (see Section IX)
218 6. Leveraging the International Medical Device Regulators Forum’s (IMDRF’s)
219 requirements for the Medical Device Single Audit Program (MDSAP) (see Section IX)
220

221 Currently accredited 3P Review Organizations should submit their application materials for
222 recognition in the manner described in Section VIII. of this guidance within six months of
223 finalization of this guidance.

224 IV. Definitions

225
226 The definitions provided below explain the terms used by FDA in the context of this guidance.
227 These terms are not intended to be applied in any context beyond this document and the 3P
228 Review Program.

229 **Device Type:** A device type or category as set forth in a section of the Code of Federal
230 Regulations, as well as a subset of such device type, such as that set forth in a product code.

231 **510(k) Submitter:** An entity or person that submits scientific and technical data in the form of a
232 510(k) submission to a 3P Review Organization for demonstrating substantial equivalence (SE)
233 of that device to a legally marketed device that is not subject to premarket approval (PMA).

234 **Final Reviewer:** An individual within the 3P Review Organization who oversees the review of
235 a 510(k) submission throughout the entire review process. The Final Reviewer is responsible for
236 ensuring that final recommendations regarding the device made by the Product Specialist
237 (defined separately) are appropriately evaluated, organized, and documented before documents
238 are sent to FDA. This individual has sufficient authority and competence within the 3P Review
239 Organization to independently evaluate the quality and acceptability of the 3P review
240 documentation. The Final Reviewer is a separate individual from the Product Specialist.
241

242 **IMDRF MDSAP Documents:** IMDRF MDSAP WG/N3 FINAL: 2013 – “Requirements for
243 Medical Device Auditing Organizations for Regulatory Authority Recognition”²⁰ and IMDRF
244 MDSAP WG/N4 FINAL: 2013 – “Competence and Training Requirements for Auditing
245 Organizations”²¹ produced by the International Medical Device Regulators Forum (IMDRF)
246 intended to implement the concept of a Medical Device Single Audit Program (MDSAP).²²
247 These documents provide criteria for audit programs that FDA believes 3P Review

²⁰ IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf>

²¹ IMDRF MDSAP Working Group N4: Competence and Training Requirements for Auditing Organizations can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf>

²² <https://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/>

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248 Organizations should follow, where applicable, and to the extent such criteria are appropriate and
249 consistent with the FD&C Act and other applicable laws and regulations.

250

251 **IMDRF Medical Device Single Audit Program:** An international program, established by
252 IMDRF, specifying a standard set of requirements for the recognition of auditing organizations
253 performing regulatory audits of medical device manufacturers and other related functions.

254

255 **NSE – Not substantially equivalent**

256

257 **Product Specialist:** An individual within the 3P Review Organization qualified to review and
258 evaluate medical devices within a specific device type(s) and who may also be qualified for a
259 specific technical or clinical specialization (e.g., biocompatibility and Ethylene Oxide (EtO)
260 sterilization), based on their scientific background and competence. This individual is the
261 primary reviewer responsible for leading the 3P Review Organization’s review team on a given
262 510(k) submission. The Product Specialist submits their recommendation and all related
263 documentation to the Final Reviewer.

264

265 **Recognition:** The process of accrediting 3P Review Organizations under section 523 of the
266 FD&C Act to review premarket notifications submitted under section 510(k) of the FD&C Act
267 (21 U.S.C. § 360k) of certain eligible devices and make recommendations to FDA regarding the
268 initial classification of such devices under section 513(f)(1) of the FD&C Act (21 U.S.C. §
269 360c(f)(1)).

270

271 **Rerecognition:** The process of renewing the accreditation of 3P Review Organizations under
272 section 523 of the FD&C Act for an additional three years.

273

274 **Recognition Criteria:** The applicable FD&C Act requirements, including the qualification
275 requirements set forth in section 523(b)(3); FDA’s recommendations described in this guidance
276 document, including those criteria contained in IMDRF MDSAP WG N3²³ and N4²⁴, (which
277 include the International Organization for Standardization (ISO)/the International
278 Electrotechnical Commission (IEC) 17021:2011 “Conformity assessment – Requirements for
279 bodies providing audit and certification of management systems”, where appropriate and
280 applicable); and the criteria to accredit or deny accreditation announced in the Federal Register.²⁵

281

282 **Recognition Denial:** The process of denying an application for accreditation submitted by a
283 potential 3P Review Organization.

284

²³ IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf>

²⁴ IMDRF MDSAP Working Group N4: Competence and Training Requirements for Auditing Organizations can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf>

²⁵ 63 FR 28388 (May 22, 1998) is available at <https://www.gpo.gov/fdsys/pkg/FR-1998-05-22/pdf/98-13799.pdf>.

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285 **Rerecognition Denial:** The process of denying an application for reaccreditation submitted by a
286 recognized 3P Review Organization.

287
288 **Recognition Withdrawal:** The process of withdrawing or suspending accreditation of a 3P
289 Review Organization in accordance with section 523(b)(2) of the FD&C Act.

290
291 **Safety Signal:** A signal represents a new potentially causal association or a new aspect of a
292 known association between a medical device and an adverse event or set of adverse events.²⁶

293
294 **SE** – Substantially equivalent or substantial equivalence

295
296 **Technical Expert:** An individual who provides specific knowledge or expertise. This
297 individual may be an employee of a 3P Review Organization or may be external as described
298 below in Sections VI.B and VII.D of this guidance, respectively.

299
300 **Third Party (3P) Review Organization:** An organization recognized by FDA to review 510(k)
301 submissions for certain eligible devices as authorized by section 523 of the FD&C Act.

302 **V. Factors Used in Determining Device Type Eligibility in** 303 **the 3P Review Program**

304
305
306 The factors FDA will consider in determining device type eligibility for the 3P Review Program
307 are as follows:

- 308
309 1. The risk of the device type, or subset of such device type.²⁷ FDA generally classifies
310 medical devices based on risks associated with the device type and whether general
311 controls are sufficient to provide a reasonable assurance of the safety and effectiveness of
312 the device or there is sufficient information to establish special controls to mitigate such
313 risks and provide such assurance. Devices are classified into one of three regulatory
314 classes: class I, class II, or class III.²⁸ In accordance with the statute, class III devices are
315 not eligible for 3P review.²⁹

316

²⁶ See Signal Management Program in “Medical Device Safety Action Plan: Protecting Patients, Promoting Public Health” at <https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM604690.pdf>

²⁷ See section 523(a)(3)(B)(i)(I)

²⁸ For more information on the classification of medical devices, please visit FDA’s website at <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHTransparency/ucm378714.htm>.

²⁹ See section 523(a)(3)(A)(i)

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- 317 2. Whether the device type, or subset of such device type, is permanently implantable, life
318 sustaining, or life supporting. Any 3P Review Organization seeking recognition for
319 review of such device types must provide a detailed public health justification explaining
320 why this device type should be eligible for 3P review³⁰ and how this will positively
321 impact public health.
- 322
- 323 3. The extent to which the device type is well understood. For example, devices with novel
324 technological characteristics, including some devices requiring complex special controls
325 initially classified through the De Novo process may be ineligible for 3P review.³¹
- 326 4. The extent to which necessary information to make a well-informed recommendation is
327 available to 3P Review Organizations. If information materially relevant to evaluating a
328 device type cannot be shared outside the agency (e.g., it is proprietary), the device type
329 may be ineligible for 3P review.
- 330 5. The extent to which the review of the device type does not require multifaceted,
331 interdisciplinary expertise. The following are examples of scenarios that would likely be
332 ineligible for 3P review due to the need for such expertise:
- 333 a. the review of some kinds of clinical data or complex non-clinical data (e.g.,
334 computational modeling);
- 335 b. a need for consultation across different organizational components, or in cross-
336 modality topics (e.g., a multi-reader clinical study) ;
- 337 c. a combination product or device type that requires review from another Center in
338 the Agency;
- 339 d. if a device type raises novel cross-labeling considerations, such as the potential
340 for off-label use of drugs (e.g., injector needles or syringes). “Cross-labeled”
341 combination products usually refer to any investigational drug, device, or
342 biological product packaged separately that according to its proposed labeling is
343 for use only with another individually specified drug, device of biological product
344 where both are required to achieve the intended use, indication, or effect.³²

345
346 However, if a device type contains simple clinical data such as sample clinical images or
347 tests using banked specimens, it may be eligible for 3P review. Most in vitro diagnostic
348 (IVD) devices are eligible for 3P review as they typically rely on simple clinical studies
349 to demonstrate SE.

³⁰ See section 523(a)(3)(B)(i)(II)

³¹ The guidance document describing the De Novo process is available on FDA’s website at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080197.pdf>

³² For more information on “cross-labeled” products, please visit FDA’s website at <https://www.fda.gov/combinationalproducts/aboutcombinationalproducts/ucm101496.htm>

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350
351 6. The availability of postmarket data suggesting that the device type is the subject of safety
352 signals. For example, if a device type is the subject of a safety communication, a high-
353 risk recall (Class I)³³, or postmarket data that indicate a safety signal, this device type
354 may be ineligible for 3P review.

355 For example, as of the date of issuance of this draft guidance, duodenoscopes have a
356 safety signal associated with their reprocessing.³⁴ Because of this safety signal, FDA may
357 remove duodenoscopes and accessories from eligibility for the 3P Review Program.
358

359 FDA will consider each of the above factors in determining device type eligibility for 3P review.
360 Furthermore, if a device type is considered eligible for 3P review, but a proposed modification to
361 the device type for a specific submission raises different concerns related to the factors listed
362 above, that submission may be determined to be ineligible for third party review.
363

364 Upon finalization of this guidance, the product code classification database³⁵ and FDA's list of
365 devices eligible for 3P review³⁶ will be updated to reflect the new eligibility factors used to
366 determine 3P eligibility for device types.

367 **VI. Review of 510(k) Submissions by 3P Review** 368 **Organizations**

369 3P Review Organizations share FDA's mission to protect and promote the public health by
370 ensuring medical devices are safe and effective for their intended uses. 3P Review Organizations
371 are responsible for reviewing and analyzing scientific and technical data in a 510(k) submission
372 to make a recommendation regarding the device to the FDA. 3P Review Organizations should
373 conduct their review of 510(k)s in the manner described in the sections below. Figure 2 identifies
374 the key steps in a 3P Review Organization's review of a 510(k) submission.³⁷
375
376
377

Figure 2: Steps in a 3P Review Organization's 510(k) Review

³³ For information on classification of recalls, please visit FDA's website at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/RecallsCorrectionsAndRemovals/default.htm>

³⁴ Information on safety signals associated with duodenoscopes is available on FDA's website at <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/ucm454630.htm>

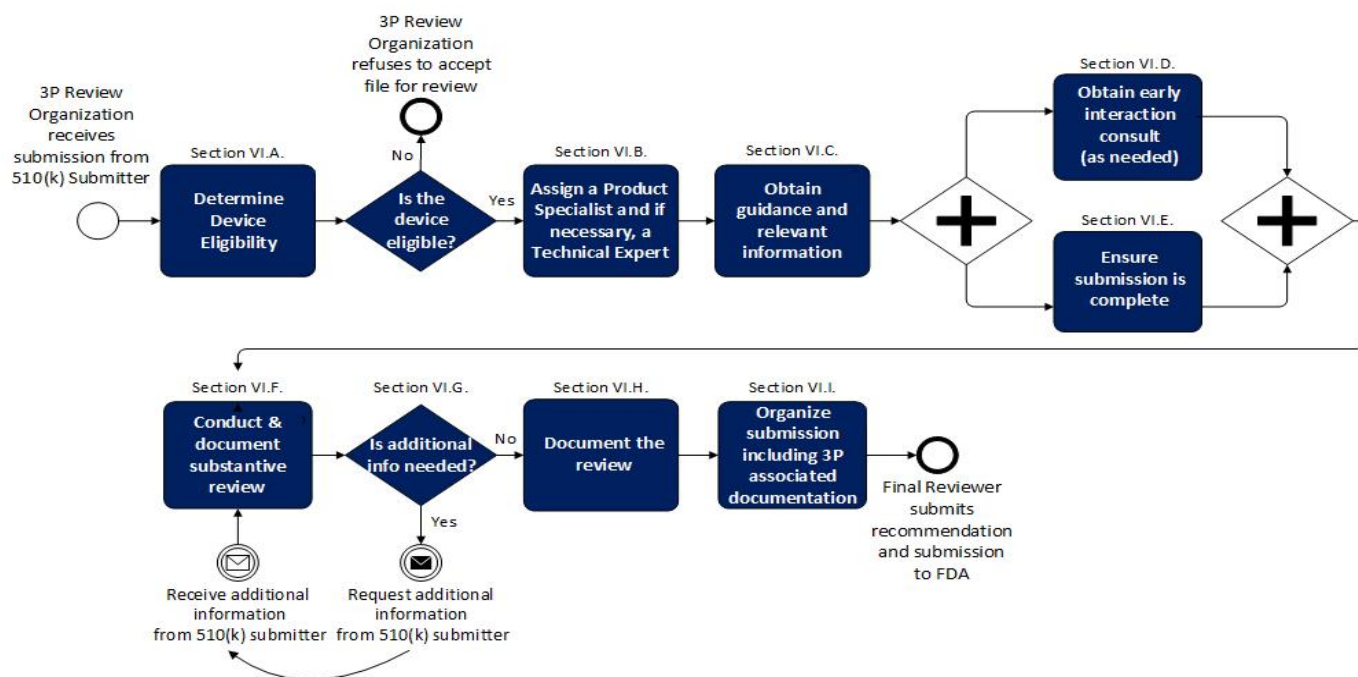
³⁵ The product code classification database is available on FDA's website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

³⁶ For a current list of eligible devices for 3P review under the 3P Review Program, please visit FDA's website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm>.

³⁷ Figure 2 uses IEC/IEC 19510: Information technology – Object Management Group Business Process Model and Notation (2013)

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379

A. Determine device eligibility for 3P review

380

381 Before reviewing a 510(k) submission, a 3P Review Organization should determine whether a
382 device type is eligible for 3P review based on review of the product code classification
383 database³⁸ or the FDA Third Party Review public website³⁹. If the device is not eligible for 3P
384 review, the 3P Review Organization should not accept the 510(k) for review from the 510(k)
385 Submitter. If the 3P Review Organization determines the device is ineligible for 3P review after
386 it has already accepted the 510(k) submission, the 3P Review Organization should immediately
387 inform the 510(k) Submitter and discontinue the review.

388 If the 3P Review Organization submits a 510(k) submission to FDA for an ineligible device, or a
389 device the 3P Review Organization is not recognized to review (see Section VIII.A), FDA will
390 place the submission on hold and notify the 3P Review Organization of FDA's eligibility
391 assessment. If the 3P Review Organization does not address eligibility concerns or withdraw the
392 submission within 180 days, FDA will delete the file. A 510(k) Submitter cannot submit a 510(k)
393 for the same device directly to FDA until the file is withdrawn voluntarily by the 3P Review
394 Organization or deleted automatically by FDA after 180 days. If a 3P Review Organization is
395 unclear regarding the eligibility status of a device, it should contact the 3P inbox at
396 3P1510K@fda.hhs.gov to seek clarification.

397

³⁸ The product code classification database is available on FDA's website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

³⁹ For a list of eligible devices for 3P review under the Third Party Review Program, please visit FDA's website at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm>.

398 **B. Assign a Product Specialist(s) and Technical Expert(s) to**
399 **conduct the substantive review of a 510(k) submission**

400
401 3P Review Organization personnel should have appropriate education, training, skills, technical
402 knowledge, qualifications, and experience to perform 510(k) reviews for the device type(s) their
403 organization is recognized to review. For additional discussion on FDA’s recommendations
404 regarding qualifications of personnel, see Section VII.C of this guidance.

405
406 Each 510(k) submission should be assigned to a Product Specialist with appropriate expertise for
407 the type of device under review. The Product Specialist may add qualified Technical Experts to
408 the review team to ensure sufficient competency in the review, if necessary. The Product
409 Specialist should document the competencies of, and the rationale for, choosing to use any
410 Technical Experts. Particular attention should be given to the expertise and impartiality of any
411 external Technical Experts. For more information on using external Technical Experts, please
412 see Section VII.D of this guidance.

413
414 **C. Obtain relevant FDA guidance(s) and information**

415
416 3P Review Organizations should review and be familiar with publicly available information
417 relevant to their review. For example:

418 1. 3P Review Organizations should review FDA’s guidance database to
419 obtain any relevant guidance documents⁴⁰ when conducting their reviews,
420 including device-specific and horizontal guidances (e.g., biocompatibility,
421 software, sterility).

422
423 2. In addition, 3P Review Organizations should be aware of any special
424 controls, which are regulatory requirements for certain class II devices, that apply
425 to that device type under review. For information on whether a device type has
426 applicable special controls, 3P Review Organizations should review the proposed
427 classification regulation of the device under Title 21 of the Code of Federal
428 Regulations (CFR)⁴¹, which will identify the mandatory special controls for a
429 particular device type.

430

⁴⁰ The guidance database search engine allows users to search the inventory of guidances available by title, words, or origin and is available on FDA’s website at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

⁴¹ The Code of Federal Regulations Title 21 database is available at <https://www.ecfr.gov/cgi-bin/ECFR?page=browse>

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431 3. 3P Review Organizations should review FDA’s postmarket databases,
432 including recalls, market withdrawals, and safety reports⁴²; Medical Device
433 Reports⁴³; and MedSun Reports⁴⁴ for the predicate device and/or the device type
434 to identify any issues with clinical use of similar devices that should be
435 considered and addressed in the review of the subject device. If potential safety
436 signals are identified by a 3P Review Organization, it should contact FDA for
437 information on current review practice.

438
439 4. 3P Review Organizations should review publicly available premarket
440 review information in FDA’s 510(k) database for information about the legally
441 marketed device (‘predicate’) to which a Submitter is comparing its device, or
442 other similar devices,⁴⁵ including Indications for Use Statements, 510(k)
443 Summaries^{46,47}, Decision Summaries (if available), and FDA decision letters. In
444 some instances, a device’s product code can also be used to identify a generic
445 category of a device and assist with the identification of similar devices. Product
446 codes can be found in FDA’s product code database.⁴⁸

447
448 5. If an applicant wishes to utilize standards, the 3P Review Organization
449 should review FDA’s guidance document titled “Appropriate Use of Voluntary
450 Consensus Standards in Premarket Submissions for Medical Devices”.⁴⁹

451
452 3P Review Organizations should request that 510(k) Submitters fully inform them of any prior
453 communications with FDA about a device under review, including but not limited to FDA
454 feedback obtained through the Pre-Submission program, unsuccessful marketing applications,
455 and other interactions. 3P Review Organizations should be familiar with the FDA Pre-
456 Submission process through the guidance document titled, “Requests for Feedback on Medical

⁴² The recalls database allows users to search for recalls and correction or removal actions initiated by a firm prior to recall classification and is available on FDA’s website at

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm>

⁴³ The MAUDE database allows users to search for Medical Device Reports and is available on FDA’s website at

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>

⁴⁴ The MedSun database allows users to search for adverse event reports from the Medical Product Safety Network and is available on FDA’s website at

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/Medsun/searchReportText.cfm>

⁴⁵ The 510(k) database search engine allows users to search all previously cleared 510(k) submissions by 510(k) number, applicant name, device name, product code, etc., and is available on FDA’s website at

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmnm.cfm>.

⁴⁶ 510(k) Summaries should be written in accordance with 21 CFR 807.92 and is available at:

https://www.ecfr.gov/cgi-bin/text-idx?SID=7272ad96195b5a401402c8b22c785d10&mc=true&node=se21.8.807_192&rgn=div8

⁴⁷ The guidance document describing 510(k) Summaries is available on FDA’s website at

<https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf>.

⁴⁸ The product code database is available on FDA’s website at

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm>.

⁴⁹ The guidance document describing the use of standards to determine substantial equivalence is available on FDA’s website at

<https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm073756.pdf>.

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457 Device Submissions: The Pre-Submission Program and Meetings with Food and Drug
458 Administration Staff⁵⁰. A 3P Review Organization should request that the authorization letter
459 from the 510(k) Submitter grant FDA permission to discuss previous submissions, identified by
460 submission numbers, with the 3P Review Organization (see Section VI. I). If applicable, the 3P
461 Review Organization should coordinate with the 510(k) Submitter to obtain and review prior
462 submission content for the device, any written feedback or meeting minutes resulting from prior
463 interactions, and any additional data, studies and/or study protocols submitted in response to
464 previous submissions by the 510(k) Submitter prior to submitting the current submission to FDA.

465
466 3P Review Organizations should also request that 510(k) Submitters submit only one 510(k) for
467 a specific device at a time.

D. Obtain early interaction consult with FDA (as needed)

468
469 3P Review Organizations should consult, as needed, with appropriate FDA staff prior to, and
470 during the review of 510(k) submissions. The early interaction consultation prior to the
471 substantive review by the 3P Review Organization is an important part of the 510(k) review
472 process. These consultations help ensure timely and consistent 510(k) reviews by assisting in
473 device eligibility determinations and identifying relevant issues and contemporary review
474 criteria.
475

476
477 In their initial recognition applications, 3P Review Organizations commit to obtaining early
478 interaction consults from FDA before reviewing a device type they have not previously reviewed
479 (see Section VIII.A). FDA also encourages early interaction consults for all 3P submissions,
480 particularly for the first review of any device type by an individual Product Specialist and for any
481 subset of device type (i.e., device type by product code) they have not recently reviewed.
482 Generally, FDA considers a recent review to be within the last six months.

483
484 Procedures on how to obtain early interaction consults will be available on the FDA Third Party
485 public website. FDA intends to respond to 3P Review Organization requests within 2 business
486 days. If that deadline cannot be met, FDA will work with the 3P Review Organization to
487 establish a reasonable timeline for a response.
488

E. Ensure a submission is administratively complete

489
490 To ensure that a submission is administratively complete, 3P Review Organizations should
491 conduct an acceptance review of the 510(k) submission based on 510(k) regulations from 21
492 CFR 807.87 to 807.100 to assess whether the 510(k) submission includes all the information
493 necessary to conduct a substantive review and to reach a recommendation (e.g., SE or NSE) as
494 defined under section 513(i) of the FD&C Act (21 U.S.C. § 360c(i)) to submit to FDA. It is
495

⁵⁰The guidance document describing the Pre-Submission program is available on FDA's website at <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm311176.pdf>.

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496 recommended that 3P Review Organizations use the Refuse to Accept (RTA) checklist for
497 510(k) submissions to make the determination regarding whether a submission is
498 administratively complete. For more information on the RTA checklist, please see FDA’s
499 guidance document titled “Refuse to Accept Policy for 510(k)s”⁵¹.

500
501 3P Review Organizations should not act as a consultant for the 510(k) Submitter. It is the
502 responsibility of the 510(k) Submitter to be familiar with the content and format requirements of
503 a 510(k) prior to submitting to a 3P Review Organization. If a Submitter is not familiar with the
504 510(k) regulatory pathway, 3P Review Organizations should direct them to resources such as
505 FDA’s guidance documents titled, “The 510(k) Program: Evaluating Substantial Equivalence in
506 Premarket Notifications [510(k)] – Guidance for Industry and FDA Staff”,⁵² and “Format for
507 Traditional and Abbreviated 510(k)s – Guidance for Industry and FDA staff”⁵³ or the Division
508 of Industry and Consumer Education in the Office of Communication and Education.⁵⁴

509
510 If the 3P Review Organization determines that a submission is administratively complete, the
511 organization should begin its substantive review of the 510(k) submission. If the 3P Review
512 Organization identifies any deficiencies in the 510(k) submission, it should contact the 510(k)
513 Submitter to request the missing information.

514 **F. Conduct the substantive review of a 510(k) submission**

515 Substantive review focuses on the evaluation of SE as defined in section 513(i) of the FD&C
516 Act. 21 CFR 807.100(b) sets forth the criteria that FDA uses to determine whether a device is
517 substantially equivalent to a legally marketed device. For information on making an SE
518 determination under the 510(k) program, please see FDA’s guidance document titled “The
519 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]”.⁵⁵
520 For information on Abbreviated and Special 510(k)s, see FDA’s guidance document titled “The
521 New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in
522 Premarket Notifications”.⁵⁶

523
524 3P Review Organizations should identify at least one independent Final Reviewer within its
525 organization who is responsible for providing a final supervisory assessment of the Product

⁵¹ The guidance document for Refuse to Accept policy is available on FDA’s website at <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm315014.pdf>.

⁵² The guidance document for the 510(k) Program is available on FDA’s website at <https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf>.

⁵³ The guidance document on the content of a 510(k) is available on FDA’s website at <https://www.fda.gov/RegulatoryInformation/Guidances/ucm084365.htm>

⁵⁴ The contact information for the Division of Industry and Consumer Education is available on FDA’s website at <https://www.fda.gov/medicaldevices/deviceregulationandguidance/contactdivisionofindustryandconsumereducation/default.htm>

⁵⁵ The guidance document used to determine the substantial equivalence of a device is available on FDA’s website at <https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf>.

⁵⁶ The guidance document for abbreviated and special 510(k) submissions is available on FDA’s website at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf>

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526 Specialist’s work before it is submitted to FDA. This individual should have sufficient authority
527 and competence to independently assess the quality and acceptability of the Product Specialist’s
528 review of the 510(k) submission.

529 If 3P Review Organizations identify any deficiencies during their substantive review, they
530 should contact the 510(k) Submitter with a request that the deficiencies be addressed. Section
531 VI.G below provides further instruction on how to identify deficiencies in a 510(k) submission.
532 When the substantive review is complete, the Product Specialist(s), Technical Expert(s), if
533 applicable, and Final Reviewer should reach an agreement on a final recommendation (e.g., SE
534 or NSE) to a predicate device before submitting the recommendation to FDA.

535 **G. Identify deficiencies in a 510(k) submission**

536
537 If a 3P Review Organization identifies any deficiencies during their review, it should contact the
538 510(k) Submitter. 3P Review Organizations may use any form of communication (i.e.,
539 telephone, facsimile, electronic mail, or letter) to resolve the matter provided confidentiality is
540 maintained and the interaction is documented. 3P Review Organizations should, however, avoid
541 the exchange of substantive data and information solely over the telephone to avoid errors that
542 may arise in the absence of a written request and response.

543 When requesting additional information from a 510(k) Submitter, 3P Review Organizations
544 should structure their additional information requests as described in FDA’s guidance document
545 titled “Developing and Responding to Deficiencies in Accordance with Least Burdensome
546 Provisions”.⁵⁷ This guidance document has examples of well-constructed deficiencies and
547 responses to FDA’s requests.

548 3P Review Organizations should document the deficiencies, the 510(k) Submitter’s response to
549 the deficiencies, and the discussion on the adequacy of the response. 3P Review Organizations
550 should also provide a copy of all written communications between the 510(k) Submitter and the
551 3P Review Organization (e.g., electronic mail, letters, summary of teleconferences). If the
552 510(k) Submitter made any modifications to the submission in response to a deficiency (e.g.,
553 revised 510(k) summary), the 3P Review Organization should document this modification and
554 request that the 510(k) Submitter provide the latest version of the 510(k) submission prior to
555 submitting to FDA. For example, if the Product Specialist requested an updated device
556 description, the latest version should be in the 510(k) submission to FDA. However, the original
557 device description and the deficiency requesting an updated device description should be found
558 in the review memo. This will ensure that FDA has the correct version of the 510(k) submission
559 on record. Proper documentation will ensure that the 3P Review Organization does not have or
560 appear to have the role of a consultant.

⁵⁷ The guidance document on developing and responding to deficiencies is available on FDA’s website at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM073680.pdf>

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H. Document a 510(k) review

561
562
563 Once a 3P Review Organization has made a final recommendation, it should prepare their review
564 documentation specifying the reasoning and steps that led to their final recommendation. 21
565 CFR 10.70 (“Documentation of significant decisions in administrative file”) provides a
566 framework that should be utilized by 3P Review Organizations. The content of the review
567 documentation will vary based on the type of 510(k) submission and device. Recommended
568 review memorandum examples for documentation purposes will be available on the FDA Third
569 Party public website.⁵⁸

570
571 If standards are referenced in a submission, FDA recommends 3P Review Organizations discuss
572 how they were utilized in the 510(k) submission in their review memorandum. A Submitter may
573 rely upon an FDA-recognized standard in their submission either ‘in general use’ or with a
574 Declaration of Conformity. General use of a consensus standard in any premarket submission
575 refers to situations where a Submitter chooses to conform to a consensus standard, but does not
576 submit a Declaration of Conformity. If a Submitter intends to submit a Declaration of
577 Conformity to an FDA-recognized consensus standard, they should state that all requirements
578 were met and identify all inapplicable requirements in a separate section in the Declaration of
579 Conformity and in the submission.

580
581 In addition to the necessary information required in a 510(k) submission⁵⁹, the review
582 memorandum should also convey how a 3P Review Organization made their recommendation
583 regarding the device. A thorough and substantive review memorandum should discuss the
584 adequacy of each section of the submission. It is not sufficient to state that a section of the
585 510(k) submission or a response to a deficiency was adequate without providing an explanation
586 of how the 3P Review Organization came to that determination.

587
588 To facilitate FDA’s review process, 3P Review Organizations should reference sections and page
589 numbers of the 510(k) submission in their review memorandum where possible. 3P Review
590 Organizations should also clearly document any deficiencies, the response to the deficiencies,
591 and the 3P Review Organization’s review of the response as indicated in Section VI.G.

592
593 The review memorandum is the only means by which FDA can understand how and why a 3P
594 Review Organization recommended a device to be SE (or NSE) to the predicate device.
595 Thorough and clear documentation will reduce the need for FDA to re-review the submission
596 itself and increase the efficiency of FDA’s final review.⁶⁰

⁵⁸Review examples will be available on FDA’s third party website:

<https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarket/submissions/thirdpartyreview/default.htm>

⁵⁹ See 21 CFR 807 Subpart E

⁶⁰ Through the MDUFA IV Commitment Letter, FDA commits to improving the 3P Review Program with a goal of eliminating routine re-review by FDA of 3P reviews:

<https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf>

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597 **I. Organize and submit a 510(k) submission including**
598 **associated 3P review documentation**

599
600 Upon completing the review of a 510(k) submission, the Final Reviewer should submit two
601 separate eCopy documents to FDA’s Document Control Center⁶¹, the 510(k) submission
602 generated by the 510(k) Submitter and the 3P review documentation generated by the 3P Review
603 Organization.

604
605 Since there are two distinct parties involved in the generation of a 3P 510(k) submission, the 3P
606 Review Organization and the 510(k) Submitter, each is subject to the eCopy requirements and
607 each must provide their own eCopy and company cover letter with an eCopy statement and
608 signature (see section 745A(b) of the FD&C Act (21 U.S.C. § 379k-1)). The 510(k) Submitter
609 should take care to submit the latest version of the 510(k) submission. This version should
610 include any documents that have been updated in response to deficiencies from the 3P Review
611 Organization. Please refer to FDA’s guidance titled “eCopy Program for Medical Device
612 Submissions”⁶² for more information on how to submit through the eCopy program.

613
614 A 3P Review Organization’s 510(k) documentation should include the following:

- 615
616 (1) A cover letter signed by the Final Reviewer that clearly identifies:
- 617 a. The purpose of the submission
 - 618 b. The name and address of the 3P Review Organization and the contact person
 - 619 c. The name, email address, and telephone number of the Final Reviewer
 - 620 d. The name and address of the 510(k) Submitter
 - 621 e. The name of the device (trade name, common or usual name, FDA classification
 - 622 regulation name, classification regulation number, and product code, as applicable)
 - 623 f. The 3P Review Organization’s recommendation (SE or NSE) with respect to the
 - 624 device
 - 625 g. The date the 3P Review Organization first received the 510(k) from the Submitter
- 626
627
628
629
630
631
632 (2) A letter signed by the 510(k) Submitter authorizing the 3P Review Organization to
633 submit the 510(k) to FDA on their behalf and authorizing the 3P Review Organization to
634
635

⁶¹ The address for CDRH’s Document Control Center is available on FDA’s website at
<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm>

⁶² The guidance document on eCopies is available on FDA’s website at
<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>.

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636 discuss the contents of the 510(k) with FDA on their behalf. This letter should also
637 authorize FDA to discuss other related submission(s) with the 3P Review Organization
638 and should include a list of these submission numbers.
639

- 640 (3) A signed certification that the reported information accurately reflects the data reviewed
641 and that no material fact has been omitted. This certification should also state that the 3P
642 Review Organization continues to meet personnel qualifications and prevention of
643 conflicts of interest criteria reviewed by FDA; that the 3P Review Organization's review
644 is based on the 510(k) that it is submitting with the review; and that the 3P Review
645 Organization understands that the submission of false information to the government is
646 prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).
647
- 648 (4) A table of contents listing the sections where the 510(k) submission and associated 3P
649 review documentation are located, along with the corresponding page numbers.
650
- 651 (5) A summary of any early interaction consults that occurred prior to the 510(k) submission
652 to FDA with the appropriate FDA staff, if appropriate (see Section VI.D of this
653 guidance).
654
- 655 (6) The 510(k) Submitter's complete 510(k) submission that conforms to FDA's
656 requirements for content and format as provided in 21 CFR part 807 subpart E. The
657 510(k) submission should be prepared by the 510(k) Submitter, not the 3P Review
658 Organization. This information should be separate from the 3P Review Organization's
659 documentation and should be the latest version. Please see Section VI.G for more
660 information. Proper documentation will ensure that the 3P Review Organization does not
661 have or appear to have the role of a consultant.
662
- 663 (7) An acceptance review of the 510(k) submission based on objective criteria using the RTA
664 checklist, discussed in Section VI.E of this guidance, to assess whether the submission is
665 administratively complete and includes all of the information necessary for the 3P
666 Review Organization to conduct a substantive review on FDA's behalf.
667
- 668 (8) A review memorandum including complete documentation of the 3P Review
669 Organization's review of the 510(k) submission as described in Section VI.H of this
670 guidance, signed by all personnel who conducted the review (generally the Product
671 Specialist(s), Technical Expert(s), when applicable, and Final Reviewer), with a decision
672 recommendation.
673

674 FDA will begin its review only after it receives all documentation listed above.
675

J. Submit additional information upon FDA's request

676
677
678 After a 3P Review Organization has submitted their 510(k) recommendation, including the
679 associated 3P review documentation, FDA will begin to review the 3P review documentation,
680 and if necessary, the 510(k) submission. If FDA determines that additional information is needed

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681 to make an SE determination, it will contact the 3P Review Organization either by telephone or
682 email.⁶³ Such requests will describe FDA’s concerns with a 510(k) submission, and identify the
683 information needed to address those concerns.

684
685 If FDA places a 510(k) submission “on hold” (i.e., officially suspends review of the submission
686 pending FDA’s receipt of additional information), it will send an email informing the 3P Review
687 Organization of the “on hold” status and request additional information. For more information
688 on a request for additional information, please see FDA’s guidance titled “FDA and Industry
689 Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and
690 Goals”.⁶⁴

691 Upon receiving a request from FDA for additional information, the 3P Review Organization
692 should:

693 (1) Promptly inform the 510(k) Submitter of FDA’s request for additional information
694 relating to the 510(k) submission and request that the 510(k) Submitter provide responses
695 to the 3P Review Organization in writing.

696
697 The 3P Review Organization should be involved in any discussions with FDA regarding
698 the request for additional information, such as if the 510(k) Submitter seeks clarification
699 or a Submission Issue Meeting with FDA;

700 (2) Thoroughly review any additional information provided by the 510(k) Submitter to
701 ensure that it adequately responds to FDA’s concerns;

702
703 (3) Document their review of the response to the deficiency by providing a clear and
704 thorough assessment of whether and how the response adequately addresses FDA’s
705 deficiency;

706
707 (4) Prepare a cover letter referencing the 510(k) number previously assigned by FDA and
708 identifying the purpose of the new submission (i.e., response to deficiencies);

709
710 (5) Send the cover letter, their additional or revised review documentation, and any
711 additional information received from the 510(k) Submitter to FDA’s Document Control
712 Center⁶⁵.

⁶³ Through the MDUFA IV Commitment Letter, FDA commits to improving the 3P Review Program with a goal of eliminating routine re-review by FDA of 3P reviews:

<https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf>

⁶⁴ The guidance document on FDA review clocks is available on FDA’s website at

<https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089738.pdf>

⁶⁵ The address for CDRH’s Document Control Center is available on FDA’s website at

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm>

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713 The 3P Review Organization must provide the two separate eCopy documents⁶⁶ (the new
714 submission eCopy document generated by the 510(k) Submitter and the eCopy document
715 generated by the 3P Review Organization). Each eCopy should be clearly marked as belonging
716 to the 3P Review Organization or the 510(k) Submitter as appropriate. For information on the
717 eCopy program, see Section VI.I of this guidance.
718

719 FDA will begin its review only after it receives the 510(k) Submitter’s response to the additional
720 information request, documentation of the 3P Review Organization’s review, and the 3P Review
721 Organization’s determination of the adequacy of the response to additional information requests.
722

K. 510(k) submission dispute resolution

723
724
725 FDA has developed guidance documents that provide an overview of the appeals processes
726 available for medical devices (see FDA’s guidances titled “Center for Devices and Radiological
727 Health Appeals Processes”⁶⁷ and “Center for Devices and Radiological Health Appeals
728 Processes: Questions and Answers About 517A”⁶⁸). The processes for reviewing and
729 reconsidering FDA decisions or actions on other 510(k) submissions are also available for 3P
730 submissions when a dispute between FDA and a 510(k) Submitter arises.
731

732 Disputes are often the result of misunderstanding or miscommunication, and FDA encourages 3P
733 Review Organizations to seek clarification, as needed, from FDA or the 510(k) Submitter during
734 a review. If the 510(k) Submitter disagrees with an FDA decision or action, the 3P Review
735 Organization should maintain impartiality and exercise care to avoid the appearance of conflict
736 of interest that may result from acting as an advocate on the 510(k) Submitter’s behalf.
737

738 If a 510(k) Submitter would like to issue a complaint against a 3P Review Organization,
739 communication should be sent to 3P510K@fda.hhs.gov.

VII. Requirements and Recommendations for Recognition and Rerecognition of Third Party Review Organizations

740
741
742
743 In this section of the guidance, FDA describes the criteria considered in recognizing 3P Review
744 Organizations to conduct premarket reviews of eligible 510(k)s as established by FDASIA.
745

⁶⁶ The guidance document describing the eCopy Program is available on the FDA’s website at <https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm313794.pdf>

⁶⁷ The guidance document describing the CDRH appeals process is available on FDA’s website at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284670.pdf>

⁶⁸ The guidance document on the CDRH appeals process, specifically regarding 517A is available on FDA’s website at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM352254.pdf>

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746 In accordance with section 523(b)(3) of the FD&C Act, a 3P Review Organization shall, at a
747 minimum, meet the following qualification requirements. Such person:

- 748
- 749 (1) May not be an employee of the Federal Government
- 750
- 751 (2) Shall be an independent organization, which is not owned or controlled by a
752 manufacturer, supplier, or vendor of devices, and which has no organizational, material,
753 or financial affiliation with such a manufacturer, supplier, or vendor.
- 754
- 755 (3) Shall be a legally constituted entity permitted to conduct the activities for which it seeks
756 recognition
- 757
- 758 (4) Shall not engage in the design, manufacture, promotion, or sale of devices
- 759
- 760 (5) The operations of such person shall be in accordance with generally accepted
761 professional and ethical business practices
- 762
- 763 (6) Shall agree, at a minimum, to include in its request for accreditation a commitment to, at
764 the time of accreditation, and at any time it is performing any review pursuant to section
765 523, it will: -
- 766 a. Certify that reported information accurately reflects data reviewed
- 767
- 768 b. Limit work to that for which competence and capacity are available
- 769
- 770 c. Treat information received, records, reports, and recommendations as proprietary
771 information
- 772
- 773 d. Promptly respond and attempt to resolve complaints regarding its activities for which
774 it is recognized
- 775
- 776 e. Protect against the use, in carrying out the review of a 510(k) submission and initial
777 classification of a device, of any officer or employee of the person who has a
778 financial conflict of interest regarding the device, and annually make available to the
779 public disclosures of the extent to which the 3P Review Organization, and the officers
780 and employees of the 3P Review Organization, have maintained compliance with
781 requirements relating to financial conflicts of interest
- 782

783 In addition to these minimum requirements set forth in the FD&C Act, a 3P Review
784 Organization should meet additional qualifications announced in the Federal Register.⁶⁹ These
785 qualifications include establishing policies designed to identify, prevent, and ensure reporting to
786 FDA, of instances of forum shopping by 510(k) Submitters. Other qualifications listed in the
787 Federal Register or that have been previously identified through guidance are discussed below.

⁶⁹ 63 FR 28388 (May 22, 1998) is available at <https://www.gpo.gov/fdsys/pkg/FR-1998-05-22/pdf/98-13799.pdf>.

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788 **A. Operational considerations**

789
790 All submissions and communications with FDA and all documentation pertaining to the review
791 of a 510(k) submitted to FDA should be in English. For foreign 3P Review Organizations, a
792 United States representative should be designated so that FDA can efficiently communicate with
793 the 3P Review Organization while conducting its review (see Section (1))
794

795 **B. Management of impartiality**

796
797 FDA expects 3P Review Organizations to be impartial and free from any commercial, financial,
798 and other pressures that might present a conflict of interest or an appearance of a conflict of
799 interest. Therefore, FDA will consider whether the potential 3P Review Organization has
800 established, documented, and executed policies and procedures to prevent any individual or
801 organizational conflict of interest or the appearance of a conflict of interest, including conflicts
802 of interests pertaining to their external Technical Experts. Policies and procedures intended to
803 address this issue should be consistent with IMDRF MDSAP WG/N3 FINAL: 2013–
804 “Requirements for Medical Device Auditing Organizations for Regulatory Authority
805 Recognition”⁷⁰ and IMDRF MDSAP WG/N4 FINAL: 2013– “Competence and Training
806 Requirements for Auditing Organizations”⁷¹. For more information on the IMDRF MDSAP, see
807 Section IX of this guidance below.
808

809 FDA recommends that 3P Review Organizations also address the following to prevent a
810 potential conflict of interest:

- 811
812 (1) 3P Review Organizations should not participate in the preparation of 510(k)s when
813 involved in 510(k) reviews. For more information, see Section VI.E of the guidance.
814
815 (2) 3P Review Organizations should not hire or contract with individuals who were
816 employed within the last twelve months by a firm who submitted a 510(k) submission
817 to either FDA or a recognized 3P Review Organization for its review. Personnel
818 should not review a medical device that they developed or helped develop.
819
820 (3) 3P Review Organizations should not promise or advertise any guarantees for FDA
821 clearance.
822

823 Information on the conflict of interest standards FDA applies to its own review personnel is
824 included in the document titled “Standards of Ethical Conduct for Employees of the Executive

⁷⁰ IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf>

⁷¹ IMDRF MDSAP Working Group N4: Competence and Training Requirements for Auditing Organizations can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf>

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825 Branch.”⁷² 3P Review Organizations are encouraged to refer to these standards in safeguarding
826 their operations against conflicts of interest.

827
828 The conflict of interest policies for a 3P Review Organization should be fully implemented and
829 signed off by the most responsible individual at the organization before any 510(k) is accepted
830 for review. When using external technical experts, see Section VII.D regarding conflicts of
831 interest safeguards.

832

C. Personnel involved in reviewing activities⁷³

833

834
835 FDA expects that 3P Review Organizations and their personnel should demonstrate knowledge
836 and experience with the following:

837

838 (1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.)

839

840 (2) The Public Health Service Act (42 U.S.C. 201 et seq.), as applicable

841

842 (3) Regulations in the Code of Federal Regulations implementing these statutes,
843 particularly 21 CFR Parts 800 through 1299.

844

845 Additionally, the 3P Review Organization should:

846

847 (4) Establish, document, and execute policies and procedures to ensure that 510(k)s are
848 reviewed by qualified personnel.

849

850 (5) Maintain records on the relevant education, training, skills, and experience of all
851 personnel who contribute to the technical review of a 510(k).

852

853 (6) Make clear written instructions for duties and responsibilities with respect to 510(k)
854 reviews available to its personnel.

855

856 (7) Employ personnel who are qualified in all the scientific disciplines addressed by the
857 510(k)s that the 3P Review Organization accepts for review.

858

859 (8) Identify at least one individual who is responsible for providing supervision over
860 510(k) reviews and who has sufficient authority and competence to assess the quality
861 and acceptability of these reviews.

862

⁷² Standards of Ethical Conduct for Employees of the Executive Branch is available at:

[https://www.oge.gov/Web/oge.nsf/0/076ABBBFC3B026A785257F14006929A2/\\$FILE/SOC%20as%20of%2081%20FR%2081641%20FINAL.pdf](https://www.oge.gov/Web/oge.nsf/0/076ABBBFC3B026A785257F14006929A2/$FILE/SOC%20as%20of%2081%20FR%2081641%20FINAL.pdf)

⁷³ Additional information on the criteria for personnel qualifications is available in the Federal Register notice published on 63 FR 28388 (May 22, 1998) at <https://www.gpo.gov/fdsys/pkg/FR-1998-05-22/pdf/98-13799.pdf>.

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863 In addressing the items enumerated above in this section, 3P Review Organizations should be
864 consistent with IMDRF MDSAP WG/N3 FINAL: 2013 – “Requirements for Medical Device
865 Auditing Organizations for Regulatory Authority Recognition”⁷⁴ and IMDRF MDSAP WG/N4
866 FINAL: 2013 – “Competence and Training Requirements for Auditing Organizations”⁷⁵. For
867 more information on the IMDRF MDSAP, see Section IX of this guidance below.
868

869 In addition, 3P Review Organizations will be expected to consult national and/or international
870 standards recognized by FDA as well as FDA guidance documents. 3P Review Organizations
871 should have the capability to interface with FDA’s electronic data systems and websites through
872 which the 3P Review Organization can search for relevant guidance documents, recognized
873 standards, predicate summaries, and publicly available information regarding adverse events and
874 recalls to provide supporting risk information when performing premarket review of similar
875 devices.
876

877 3P Review Organizations must certify in their application that designated personnel will attend
878 FDA’s training for recognition and rerecognition (see Section VIII.A of this guidance and the
879 Federal Register notice published on May 22, 1998 (63 FR 28388)). 3P Review Organizations
880 are expected to complete training before conducting any 510(k) reviews under the program. FDA
881 will not accept 510(k) reviews and recommendations from 3P Review Organizations that have
882 failed to have at least one designated person attend a FDA training session for recognition.
883

884 3P Review Organizations should be prepared to conduct technically competent 510(k) reviews
885 before requesting recognition by FDA. FDA recommends persons involved in a 510(k)
886 submission review at a 3P Review Organization meet the appropriate qualifications (i.e.,
887 specialized education or experience) provided in this guidance. When a 3P Review Organization
888 requests to expand the scope of device types for which it may review 510(k) submissions, it
889 should ensure through its policies and procedures in place that its staff are qualified in the
890 scientific disciplines for the new device types.
891

D. Use of external Technical Experts

892
893
894 The following are FDA’s recommendations when 3P Review Organizations use an external
895 Technical Expert:

- 896
897 (1) External Technical Experts should meet the same standards as those who work within
898 the 3P Review Organization, such as freedom from conflicts of interest
899
900 (2) External Technical Experts should be discouraged from subcontracting parts of their
901 contract to subcontractors

⁷⁴ IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf>

⁷⁵ IMDRF MDSAP Working Group N4: Competence and Training Requirements for Auditing Organizations can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf>

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902
903 (3) 3P Review Organizations should maintain records of the qualifications of external
904 Technical Experts, in addition to evidence of regular monitoring of the established
905 competence and the degree of fulfillment of the outsourced work
906

907 To ensure that 3P Review Organizations have sufficient competence among their own staff, there
908 should be at least one qualified Product Specialist per device type that the 3P Review
909 Organization is recognized to review. This is to ensure that there is not excessive reliance on
910 external expertise by a 3P Review Organization and to enable appropriate oversight of the
911 qualifications of external Technical Experts by 3P Review Organizations.
912

913 In addressing the items above, 3P Review Organizations should be consistent with IMDRF
914 MDSAP WG/N3 FINAL: 2013 – “Requirements for Medical Device Auditing Organizations for
915 Regulatory Authority Recognition”⁷⁶ and IMDRF MDSAP WG/N4 FINAL: 2013 –
916 “Competence and Training Requirements for Auditing Organizations”⁷⁷. For more information
917 on the IMDRF MDSAP, see Section IX of this guidance below.
918

E. Confidential information

919
920 A 3P Review Organization is required to treat information received, records, reports, and
921 recommendations as proprietary information (see sections 301(y)(2) and 523(b)(3)(F)(iii) of the
922 FD&C Act). Also, in accordance with 21 CFR 807.95, when a 510(k) is submitted by a device
923 manufacturer to FDA, FDA will in general not publicly disclose that submission. Thus, a 3P
924 Review Organization should not publicly disclose a 510(k) submission for a device that is not
925 currently on the market and where the intent to market the device has not been disclosed.
926
927

928 FDA will determine whether information submitted to FDA by a 3P Review Organization can be
929 released in accordance with the Freedom of Information Act (21 CFR part 20) and 21 CFR
930 807.95, regarding confidentiality of information in 510(k)s. In general, 510(k) reviews submitted
931 by 3P Review Organizations will be available for disclosure by FDA after the agency has issued
932 an SE decision for a device, unless the information is exempt from public disclosure under 21
933 CFR part 20 or 21 CFR 807.95. If necessary, a copy of the 510(k) will be provided to the
934 manufacturer for predislosure notification according to §20.61.
935

936 In addition, information submitted by a 3P Review Organization to obtain recognition or
937 rerecognition from FDA will be available for disclosure, unless exempted under 21 CFR part 20.
938

⁷⁶ IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf>

⁷⁷ IMDRF MDSAP Working Group N4: Competence and Training Requirements for Auditing Organizations can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf>

939 **F. Complaints regarding 510(k) Submitters**

940
941 The 3P Review Organization should send to FDA via e-mail to 3P510K@fda.hhs.gov
942 information on any complaint (e.g., whistleblowing) it receives about a 510(k) Submitter that
943 could indicate an issue related to the safety or effectiveness of a medical device or a public
944 health risk.

945
946 **G. Third Party Review Organization recordkeeping**

947
948 Pursuant to section 704(f) of the FD&C Act, a 3P Review Organization must maintain records
949 that support their initial and continuing qualifications to receive FDA recognition. These records
950 must include the following:

- 951
- 952 (1) Documentation of the training and qualifications of the 3P Review Organization and
953 its personnel;
 - 954 (2) The procedures used by the 3P Review Organization for handling confidential
955 information;
 - 956 (3) The compensation arrangements made by the 3P Review Organization; and
957
 - 958 (4) The procedures used by the 3P Review Organization to identify and avoid conflicts of
959 interest.
960
961

962
963 In addition to these recordkeeping requirements, 3P Review Organizations should retain the
964 following records for at least three years (3) following the submission of a 510(k) for review to
965 FDA:

- 966
- 967 (1) Copies of all 510(k) reviews and associated correspondence;
 - 968 (2) Information on the identity and qualifications of all personnel who contributed to the
969 technical review of each 510(k); and
970
 - 971 (3) Other relevant records.
972

973
974 In addressing the items enumerated above, 3P Review Organizations should be consistent with
975 IMDRF MDSAP WG/N3 FINAL: 2013 – “Requirements for Medical Device Auditing
976 Organizations for Regulatory Authority Recognition”⁷⁸ and IMDRF MDSAP WG/N4 FINAL:

⁷⁸ IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf>

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977 2013 – “Competence and Training Requirements for Auditing Organizations”⁷⁹. For more
978 information on the IMDRF MDSAP, see Section IX of this guidance.

979
980 In accordance with section 704(f)(1) of the FD&C Act, 3P Review Organizations must make the
981 records specified in that section available upon request by an officer or employee of FDA. 3P
982 Review Organizations shall permit the FDA officer or employee at all reasonable times to have
983 access to, copy, and/or verify these records. Within 15 days of receipt of a written request from
984 FDA, 3P Review Organizations must make copies of the requested records available at the place
985 FDA designates (see section 704(f)(2) of the FD&C Act). If FDA’s monitoring of the 3P Review
986 Program, such as a review of compensation arrangements between 3P Review Organizations and
987 510(k) Submitters, reveals that 510(k) Submitters are developing business relationships with 3P
988 Review Organizations that call into question the independence or objectivity of a 3P Review
989 Organizations, FDA will consider limiting a Submitter's choice of 3P Review Organizations.
990 Business relationships that may undermine the independence or objectivity of a 3P Review
991 Organization include, for example, contracts between a manufacturer and a 3P Review
992 Organization that represent a significant share of the 3P Review Organization's income.

993
994 Section 523(b)(3)(F)(iv) requires 3P Review Organizations to agree that they will promptly
995 respond and attempt to resolve complaints regarding its activities for which it is accredited. FDA
996 recommends that 3P Review Organizations establish a recordkeeping system for tracking the
997 submission of those complaints and how those complaints were resolved, or attempted to be
998 resolved.

999 **VIII. Content and Format of an Application for Initial** 1000 **Recognition and Rerecognition as a 3P Review Organization**

1001
1002 This section of the guidance provides FDA’s recommendations on what should be included in an
1003 application to FDA for recognition as a 3P Review Organization.

1004
1005 The 3P Review Organization should inform FDA promptly if they would like to suspend,
1006 withdraw, cancel or reduce the scope of their program. FDA will adjust recognition or
1007 rerecognition as appropriate.
1008

1009 **A. Initial Recognition** 1010

⁷⁹ IMDRF MDSAP Working Group N4: Competence and Training Requirements for Auditing Organizations can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf>

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1011 Organizations that wish to become recognized as 3P Review Organizations under section 523 of
1012 the FD&C Act should send their applications to FDA at the following address. To facilitate
1013 review of the application, FDA strongly encourages submission of an eCopy.⁸⁰
1014

1015 CDRH Third Party Premarket Review Program
1016 U.S. Food and Drug Administration
1017 Document Control Center (DCC) – WO66-G609
1018 10903 New Hampshire Avenue,
1019 Silver Spring, Maryland 20993 USA.
1020 3P510K@fda.hhs.gov
1021

1022 FDA will acknowledge receipt with an email to the applicant’s designated contact person when
1023 the application is received. FDA will review these materials and respond within 60 calendar
1024 days⁸¹ of the date of the receipt of the application with a decision to recognize or deny
1025 recognition, or a request for additional information. FDA may deem the application incomplete
1026 and deny recognition if the applicant fails to respond to FDA’s request for additional information
1027 in a timely manner.
1028

1029 The following information should be submitted in an application for FDA’s consideration:
1030
1031

1032 **(1) Administrative information**

- 1033 a. The name and mailing address of the 3P Review Organization seeking
1034 recognition;
- 1035 b. The telephone number, email address, and fax number of the contact
1036 person. The contact person should be the person to whom questions
1037 about the content of the application may be addressed and the person to
1038 whom a letter of determination and general correspondence will be
1039 directed. Foreign organizations should also identify the name, address,
1040 telephone number, email address, and fax number of an authorized
1041 representative located within the United States that will serve as the 3P

⁸⁰ For information on the eCopy program, please see FDA’s guidance titled “eCopy Program for Medical Device Submissions” available on FDA’s website at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313794.pdf>.

⁸¹ FDA uses calendar days when measuring on-time performance of user-fee supported premarket medical device submission reviews. See, “MDUFA Performance Goals and Procedures, Fiscal Years 2018 through 2022” at <https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM535548.pdf> for more information.

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- 1042 Review Organization’s contact with FDA (see also Section VII.A of this
1043 guidance);
- 1044 c. The name and title of the most responsible individual at the 3P Review
1045 Organization;
- 1046 d. A brief description of the 3P Review Organization, including: type of
1047 organization (e.g., not-for-profit institution, commercial business, other
1048 type of organization); size of organization (number of employees);
1049 number of years in operation; nature of work (e.g., testing or
1050 certification laboratory); and information regarding ownership (i.e.,
1051 name of owner(s) and extent of ownership), operation, control of
1052 organization, and other related information sufficient for FDA to assess
1053 its degree of independence from entities such as device manufacturers
1054 and distributors;
- 1055 e. A listing of any national, state, local, or other recognition; and
- 1056 f. A list of the device types the applicant seeks to review by product codes
1057 or classification regulation name and regulation. Please refer to the FDA
1058 Third Party public website⁸² for devices that are eligible for 3P review.

(2) Prevention of conflicts of interest

1059
1060
1061 A copy of the written policies and procedures established by the 3P Review Organization to
1062 ensure that the 3P Review Organization and its employees (including external technical experts,
1063 contractors and individual contract employees) involved in the evaluation of 510(k)s are free
1064 from conflicts of interest, and to prevent any individual or organizational conflict of interest, or
1065 appearance of conflict of interest that might affect the review process.

(3) Personnel qualifications

1066
1067
1068 A list of personnel who will be involved in the preparation of the 3P Review Organization’s
1069 510(k) recommendations, including Product Specialists, Technical Experts, external Technical
1070 Experts, and Final Reviewers. Applicants should demonstrate that these personnel are technically
1071 competent to conduct 510(k) reviews and should document the following in their application:

⁸² Information on third party eligible device types is available on FDA’s website:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfThirdParty/current.cfm>

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- 1072 a. The written policies and procedures established to ensure 510(k)s are
1073 reviewed by qualified personnel;
- 1074 b. The written instructions for the duties and responsibilities of personnel
1075 with respect to 510(k) reviews;
- 1076 c. The written personnel standards established to ensure that designated
1077 personnel are qualified in all of the scientific disciplines presented by the
1078 510(k)s for devices for which the 3P Review Organization is applying
1079 for its review;
- 1080 d. The documentation (e.g., curricula vitae or CVs) to establish that the
1081 reviewers of 510(k)s (i.e., product specialists and technical experts) and
1082 other involved non-supervisory personnel meet the Recognition Criteria
1083 for qualified personnel. This includes documentation of education,
1084 training, skills, abilities, and experience, including specialized education
1085 and experience needed for the review of devices for which the 3P
1086 Review Organization is applying for its review;
- 1087 e. The documentation (e.g., CVs) to establish that the supervisor(s) of
1088 510(k) reviewers (i.e., Final Reviewer) have sufficient authority and
1089 meet the Recognition Criteria for qualified supervisory personnel. This
1090 includes documentation of education, training, skills, abilities, and
1091 experience, including specialized education and experience needed for
1092 the review of class II devices for which the 3P Review Organization is
1093 applying for its review; and
- 1094 f. A description of the management structure, or, if an external technical
1095 expert is used for 510(k) reviews, the external technical expert's
1096 management structure. The application should describe the position of
1097 the individual(s) providing supervision within the management structure
1098 and explain how that structure provides for the supervision of 510(k)
1099 reviewers and other personnel involved in the review process.

(4) Certification statements

1100
1101 In order to address all relevant statutory requirements, and to support FDA's commitment to
1102 eliminate routine re-review of 3P submissions, the applicant must provide a statement in their
1103 application, signed by the most responsible individual at the organization, certifying that the 3P
1104 Review Organization has committed at the time of accreditation and at any time it is performing
1105 any 3P review that it:
1106

- 1107 a. Will report information that accurately reflects data reviewed;
- 1108 b. Will limit work and reviews to that for which competence and capacity
1109 are available, including conducting 510(k) reviews in accordance with

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- 1110 the policies and procedures it has established regarding review of
1111 510(k)s by qualified personnel;
- 1112 c. Will treat any information, records, reports, and recommendations that
1113 they may receive as proprietary and confidential information;
- 1114 d. Will promptly respond and attempt to resolve complaints regarding the
1115 activities for which it is recognized;
- 1116 e. Will protect against conflicts of interests in accordance with policies and
1117 procedures it has established relating to prevention of financial conflicts
1118 of interests, and annually make available to the public disclosures of the
1119 extent to which the person, and the officers and employees of the person,
1120 have maintained compliance with requirements relating to financial
1121 conflicts of interest;
- 1122 FDA also expects the applicant to certify in its application that at all times, it:
- 1123 a. Will demonstrate conformity while recognized by FDA with the
1124 requirements of section 523 of the FD&C Act;
- 1125 b. Will maintain records in a manner consistent with Section VII.G of this
1126 guidance;
- 1127 c. Will comply with the eCopy requirements⁸³ for premarket submissions
1128 as described in the guidance document titled, “eCopy Program for
1129 Medical Device Submissions,” as discussed in Section VI.I of this
1130 guidance;
- 1131 d. Commits that their most responsible person or designee(s) will have
1132 completed FDA training prior to performing any reviews by the 3P
1133 Review Organization, and agrees that their most responsible person or
1134 designee(s) will attend such training when offered and applicable;
- 1135 e. Will contact FDA for early interaction consults before reviewing any
1136 subset of device type (by respective product code) that they have not
1137 reviewed as encouraged in Section VI.D of this guidance; and
- 1138 f. Will commit to only accepting reviews where the 510(k) Submitters
1139 certified that any relevant prior communications with FDA are
1140 disclosed.

1141 **B. Rerecognition**

1142

⁸³ See section 745A(b) of the FD&C Act.

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1143 In accordance with section 523(b)(2)(D) of the FD&C Act, a 3P Review Organization’s
1144 recognition by FDA will sunset 3 years from the date the recognition was granted under section
1145 523 of the FD&C Act. To continue conducting 3P 510(k) reviews beyond 3 years from the date
1146 of the last recognition or rerecognition, the 3P Review Organization must obtain rerecognition.
1147

1148 Requests for rerecognition will be handled in the same manner as initial recognition requests.
1149 Accordingly, rerecognition applications should follow the format described in Section VIII.A of
1150 this guidance. For rerecognition, FDA may also consider the past premarket review performance
1151 of the 3P Review Organization and any information that comes to FDA’s attention about the
1152 status of the 3P Review Organization’s recognition, including information from an audit.⁸⁴
1153

1154 FDA recommends that 3P Review Organizations apply for rerecognition a minimum of 60
1155 calendar days before their recognition status expires to prevent any lapse in recognition. A 3P
1156 Review Organization may request a rerecognition earlier if it so chooses.
1157

C. Recognition or Rerecognition Denial

1158
1159 A 3P Review Organization that wishes to request a reconsideration of a recognition denial or
1160 rerecognition denial may make a written request to FDA. For information about the appeals
1161 processes, please see FDA’s guidance titled “Center for Devices and Radiological Health
1162 Appeals Processes”.⁸⁵ A written appeal should be submitted to the CDRH Ombudsman at:
1163
1164

1165 CDRH Ombudsman
1166 Center for Devices and Radiological Health
1167 Food and Drug Administration
1168 WO32 Room 4282
1169 10903 New Hampshire Avenue
1170 Silver Spring, Maryland 20993 USA

IX. Suspension or Recognition Withdrawal

1171
1172 Section 523(b)(2)(B) of the FD&C Act authorizes FDA to suspend or withdraw recognition of
1173 any 3P Review Organization, after providing notice and an opportunity for an informal hearing,
1174 when the 3P Review Organization is substantially not in compliance with the requirements of
1175 section 523 of the FD&C Act, poses a threat to public health or fails to act in a manner that is
1176 consistent with the purposes of section 523 of the FD&C Act.
1177
1178

⁸⁴ See section 523(b)(2)(C)

⁸⁵ Information on the appeals process for CDRH is available on FDA’s website at
<https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM352254.pdf> and <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm284670.pdf>.

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1179 Under section 301(y)(1) of the FD&C Act, the following actions are prohibited by a 3P Review
1180 Organization:

- 1181
- 1182 (1) Submission of a report or recommendation that is false or misleading in any material
1183 respect;
 - 1184
 - 1185 (2) Disclosure of confidential information or any trade secrets without the express written
1186 consent of the person who submitted such information or secrets to the 3P Review
1187 Organization; and
 - 1188
 - 1189 (3) Receipt of a bribe in any form or doing any corrupt act associated with a responsibility
1190 delegated to the 3P Review Organization under the FD&C Act.
- 1191

1192 FDA will perform an assessment of each 3P Review Organization on a periodic or “for cause”
1193 basis as part of its auditing to ensure 3P Review Organizations continue to meet the standards of
1194 recognition (see section 523(b)(2)(C) of the FD&C Act). Generally, assessments will involve
1195 inspecting a 3P Review Organization’s facility and/or records to ensure that the 3P Review
1196 Organization is operating in accordance with the procedures, qualifications, and certifications
1197 specified in the 3P Review Organization’s application and the FD&C Act.

1198

1199 Furthermore, FDA will periodically evaluate completed premarket reviews of 510(k)s submitted
1200 to FDA under the 3P Review Program and will provide feedback to Product Specialists and the
1201 Final Reviewer of 3P Review Organizations following its audits.

1202

1203 3P Review Organizations should continue to demonstrate technical competency to maintain
1204 recognition. If monitoring of a 3P Review Organization reveals nonconformity with section 523,
1205 a threat to the public health, or a failure to act in a manner that is consistent with the purposes of
1206 section 523 of the FD&C Act, FDA may take steps to suspend or withdraw recognition of the 3P
1207 Review Organization, after providing notice and an opportunity for an informal hearing. See
1208 section 523(b)(2)(B) of the FD&C Act.

1209 **IX. Leveraging the International Medical Device**
1210 **Regulators Forum’s (IMDRF’s) requirements for the**
1211 **Medical Device Single Audit Program (MDSAP)**

1212

1213 In February 2011, the IMDRF was convened to discuss future directions in medical device
1214 regulatory harmonization. The IMDRF is a voluntary group of medical device regulators from
1215 around the world, including representatives from the FDA, who collaborate to build on the strong
1216 foundational work of the Global Harmonization Task Force on Medical Devices. The purpose of
1217 the IMDRF is to accelerate international medical device regulatory convergence.

1218

1219 The IMDRF developed the Medical Device Single Audit Program (MDSAP). Program details
1220 are outlined in a collection of documents finalized from 2013 through 2015 and available on the

Contains Nonbinding Recommendations

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1221 IMDRF website.⁸⁶ These documents provide the fundamental building blocks of a 3P auditing
1222 program by providing criteria for the recognition and monitoring of entities that perform
1223 regulatory audits and other related functions.
1224

1225 There are many shared elements in FDA’s statutory and regulatory criteria for 3P Review
1226 Organizations and IMDRF MDSAP WG/N3 FINAL: 2013– “Requirements for Medical Device
1227 Auditing Organizations for Regulatory Authority Recognition”⁸⁷ and IMDRF MDSAP WG/N4
1228 FINAL: 2013 – “Competence and Training Requirements for Auditing Organizations.”⁸⁸ These
1229 two documents focus on requirements of an auditing organization and individuals performing
1230 regulatory audits and other related functions under the respective medical device legislation,
1231 regulations, and procedures required in its regulatory jurisdiction.
1232

1233 Due to these similarities, FDA believes that potential 3P Review Organizations in compliance
1234 with the MDSAP program are to be likely in compliance with most FDA 3P Review
1235 Organization requirements and meet FDA’s recommendations outlined in this guidance
1236 document. Such organizations do not necessarily need to generate new documentation for FDA,
1237 but rather can leverage existing documents in their applications to FDA and for ongoing
1238 recordkeeping. As there are some differences between terms used by various international
1239 organizations, Table 1 below provides an explanation of how terms used in the IMDRF MSDAP
1240 documents should be interpreted in relation to FDA personnel and 3P Review Organizations for
1241 purposes of the 3P Review Program.
1242

1243 **Table 1. Relationship of different terms used in the IMDRF documents, by 3P Review**
1244 **Organizations, and by FDA.**

IMDRF MDSAP Equivalent	3P Review Organization Equivalent	FDA Equivalent
Auditor	Product Specialist	Lead Reviewer
Regulatory Authority	FDA Representatives	FDA Representatives to the 3P Review Program
Audit	Review	Review
Final Reviewer	Final Reviewer	Branch Chief or equivalent
Technical Expert	Technical Expert	FDA Internal Consultant (e.g., statistician)

1245

⁸⁶ As of the publication of this draft guidance document, the IMDRF has published five documents related to MDSAP. All the IMDRF MDSAP documents are available on the IMDRF website at: <http://imdrf.org/documents/documents.asp>.

⁸⁷ IMDRF MSAP Working Group N3: Requirements for Medical Device Auditing Organizations for Regulatory Authority Recognition can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-auditing-requirements-140901.pdf>

⁸⁸ IMDRF MDSAP Working Group N4: Competence and Training Requirements for Auditing Organizations can be found at <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-competence-and-training-requirements-140901.pdf>