Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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For questions about this document, contact the DHT5B: Division of Neuromodulation and Physical Medicine Devices at 301-796-6610 or Ian Marcus at Ian.Marcus@fda.hhs.gov.

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U.S. Department of Health and Human Services
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Preface

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Cutaneous Electrodes for Recording Purposes – Performance Criteria for Safety and Performance Based Pathway

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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

I. Introduction

This draft guidance provides performance criteria for cutaneous electrodes in support of the Safety and Performance Based Pathway.[1] Under this framework, submitters planning to submit a 510(k) using the Safety and Performance Based Pathway for cutaneous electrodes for recording purposes will have the option to use the performance criteria proposed in this draft guidance to support substantial equivalence, rather than a direct comparison of the performance of the subject device to that of a predicate device.

For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[2] For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.[3]

[1] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway

[2] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

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

II. Scope/Device Description

The cutaneous electrodes that are the subject of this guidance are non-invasive, single use electrodes intended to be used on normal, healthy, clean, intact skin for recording purposes. These devices are Class II and are regulated under 21 CFR 882.1320, with the product code GXY (Electrode, Cutaneous).

Intended Use/Indications for Use:
The cutaneous electrodes that fall within the scope of this guidance document are intended for non-invasive recording purposes only. These devices are intended to be applied directly to a patient's skin to record physiological signals (e.g., electroencephalogram, electromyography). These electrodes should be applied only to normal, intact, clean, and healthy skin with an electroconductive media.

Cutaneous electrodes with the following intended uses are not eligible for the Safety and Performance Based Pathway via this guidance:

- To deliver stimulation
- For use in an MR environment
- For an intended use regulated by a different regulation (e.g., 21 CFR 870.2360, 21 CFR 878.4400)
- To be reused (i.e., not single use)
- Dry electrodes (i.e., no electroconductive media is used)

Device Design Characteristics:
The cutaneous electrodes that fall within the scope of this guidance document are designed for non-invasive use on intact skin. A cutaneous electrode may incorporate electroconductive media (e.g., pre-gelled). If the cutaneous electrode does not incorporate electroconductive media in its design, the cutaneous electrode should successfully meet the Testing Performance Criteria (described in this guidance) with the legally marketed electroconductive media (21 CFR 882.1275) intended to be used with electrode. The electrode should be used with electroconductive media. Please note that this guidance document's scope does not cover electroconductive media devices (21 CFR 882.1275). Additionally, this guidance document does not include needle electrodes (21 CFR 882.1350).

The electrode design (e.g., size, shape, type) should be commensurate to the site of application and the intended use, as these attributes may affect the safety and effectiveness of the recording. Additionally, the size and spacing of the electrodes should be appropriate for the indicated patient population (e.g., children, adults).

Where FDA determines that additional data are necessary to make these determinations, the Agency may, on a case-by-case basis, review that data before determining whether or not the device is appropriate for the Safety and Performance Based Pathway. In situations, where you determine that additional testing outside of those identified in this guidance are necessary to make a determination regarding eligibility into the Safety and Performance Based Pathway, we would encourage sponsors to submit a Pre-Submission[4] to engage in discussion with FDA prior to submission of the 510(k).

III. Testing Performance Criteria

If your device is appropriate for submission through the Safety and Performance Based Pathway, and you choose to use that option, you do not need to provide direct comparison testing against a legally marketed predicate device to demonstrate substantially equivalent performance characteristics. To ensure that the performance criteria outlined in this guidance remain contemporary and take into account relevant data from recent clearances, FDA recommends that you provide a results summary for all tests evaluated in addition to the other submission information (e.g., Declaration of Conformity (DoC)) identified for each test or evaluation below. Unless otherwise identified in the submission information sections below, test information such as results summary, test protocols, or complete test reports should be submitted as part of the 510(k) as described in FDA's guidance Safety and Performance Based Pathway.[5] For additional information regarding the submission of non-clinical bench testing information, please see FDA's guidance Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions.[6]

Electrode Characterization

1. **Test name:** AC Impedance (Electrical Performance)
   Methodology: FDA currently-recognized version of American National Standards Institute/Association for the Advancement of Medical Instrumentation (ANSI/AAMI) EC12 *Disposable ECG Electrodes*
   Performance Criteria: 2 kOhms Maximum (Average Value of 10-Hz impedance for 12 electrode pairs), 3 kOhms Maximum (Individual pair impedance)
   Performance Criteria Source: ANSI/AAMI EC12 *Disposable ECG Electrodes*
   Submission Information: DoC

2. **Test name:** Offset Voltage (Electrical Performance)
   Methodology: ANSI/AAMI EC12 *Disposable ECG Electrodes*
   Performance Criteria: 100 mV Maximum

[4] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program
[5] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/safety-and-performance-based-pathway
[6] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket

Performance Criteria Source: ANSI/AAMI EC12 *Disposable ECG Electrodes*
Submission Information: DoC

3. **Test name:** Combined offset instability and internal noise (Electrical Performance)
Methodology: ANSI/AAMI EC12 *Disposable ECG Electrodes*
Performance Criteria: 150 μV Maximum
Performance Criteria Source: ANSI/AAMI EC12 *Disposable ECG Electrodes*
Submission Information: DoC

4. **Test name:** Bias Current Tolerance (DC Voltage Offset) (Electrical Performance)
Methodology: ANSI/AAMI EC12 *Disposable ECG Electrodes*
Performance Criteria: 100 mV Maximum
Performance Criteria Source: ANSI/AAMI EC12 *Disposable ECG Electrodes*
Submission Information: DoC

5. **Test name:** Adhesive Performance
Methodology: FDA currently-recognized version of International Electrotechnical Commission (IEC) 60601-2-2 *Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories*, (a) Pull Test, (b) Conformability Test, (c) Fluid Tolerance Test
Performance Criteria: (a) No more than 5% of the electrodes' adhesive area should separate from the skin surface in at least 90% of the tests. (b) No more than 10% of the adhesive area of the electrode should have separated from the skin surface at 1 hour after application. (c) No more than 10% of the adhesive area of the electrode should have separated from the skin surface within 15 minutes after the saline is poured.
Performance Criteria Source: IEC 60601-2-2, (a) Pull Test, (b) Conformability Test, (c) Fluid Tolerance Test
Submission Information: DoC

6. **Test name:** Shelf Life
Methodology: Perform electrode characterization tests 1-5 of this guidance document (above) with device samples either real-time or accelerated aged to within 30 days of the labeled expiration date
Performance Criteria: Electrode characterization performance criteria identified in tests 1-5 of this guidance document (above)
Performance Criteria Source: IEC 60601-2-2 and ANSI/AAMI EC12 *Disposable ECG Electrodes*
Submission Information: DoC

If electrode lead wires are included:

7. **Test name:** Conductive Connection Compliance (Patient Leads or Patient Cables)
Methodology: FDA currently-recognized version of ES 60601-1: *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance*

Performance Criteria: Conformance to the ES 60601-1 consensus standard
Performance Criteria Source: ES 60601-1
Requirement: Percutaneous leads or other cables having a conductive connection to a patient must comply with the performance standard in 21 CFR 898.12, which states that any connector in a cable or electrode lead wire having a conductive connection to a patient shall be constructed in such a manner as to comply with subclause 56.3(c) of the following standard: International Electrotechnical Commission (IEC) 601-1 *Medical Electrical Equipment Part 1 – General requirements for safety (1988, amendment No.1, 1991, amendment No. 2, 1995).* However, FDA believes conformance to applicable subclauses in the currently FDA-recognized version of the ES 60601-1 *Medical Electrical Equipment Part 1 – General requirements for basic safety and essential performance* (2005, MOD) standard would provide the same level of protection of the public health and safety from unintended electrical shock as the FDA performance standard in 21 CFR 898.12, and that conformity to this currently FDA-recognized standard would be sufficient to meet the performance standard in 21 CFR 898.12. Therefore, firms may submit a DoC to this currently FDA-recognized standard.[7]
Submission Information: DoC

Biocompatibility Evaluation

To identify the biocompatibility endpoints to include as part of your biocompatibility evaluation you should use Attachment A of CDRH's guidance Use of International Standard ISO 10993-1, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,[8] referred to in the rest of this document as the CDRH Biocompatibility Guidance for brevity. FDA considers the devices covered by this guidance to be categorized as "Surface Devices" with intact skin contact, and you should assess the endpoints below per Attachment A of the CDRH Biocompatibility Guidance.

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity

Rationale in Lieu of Testing: If the subject device is manufactured from the identical raw materials using identical manufacturing processes as a predicate device with the same type and duration of tissue contact, and any changes in geometry are not expected to impact the biological response, this is typically sufficient to establish substantially equivalent biocompatibility, if documentation such as that outlined in Attachment F of the CDRH Biocompatibility Guidance is also provided.

Testing: If you determined that testing is needed to address some or all of the identified endpoints, FDA recommends that complete test reports be provided for all tests performed unless a declaration of conformity without supplemental information can be appropriately provided, per

[7] See Section 514(c) of Federal Food, Drug and Cosmetic Act.
[8] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and

Attachment E of the CDRH Biocompatibility Guidance. Any test-specific positive, negative, and/or reagent controls should perform as expected, and protocol deviations should be thoroughly described and justified; however, note that certain protocol deviations may invalidate comparison to the performance criteria listed below and require submission of a Traditional, Special, or Abbreviated 510(k).

8. **Test name:** Biocompatibility endpoints (identified from CDRH Biocompatibility Guidance)
   Methodology: FDA currently-recognized versions of biocompatibility consensus standards
   Performance Criteria: All direct or indirect tissue contacting components of the device and device-specific instruments should be determined to have an acceptable biological response.
   Performance Criteria Source: The CDRH Biocompatibility Guidance
   Additional Considerations: For any biocompatibility test samples with an adverse biological response, the biocompatibility evaluation should explain why the level of toxicity seen is acceptable. Some comparison testing against a legally marketed predicate may be necessary (and is considered acceptable under the Safety and Performance Based Pathway) to support such a rationale as explained in the CDRH Biocompatibility Guidance. For standard biocompatibility test methods that include comparison device control samples, the legally marketed comparison device control samples should perform as expected, as specified above for the subject device samples.
   Submission Information: Refer to CDRH Biocompatibility Guidance