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DRAFT GUIDANCE FOR CORTICAL ELECTRODE 510(K) CONTENT

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This guidance document may contain references to addresses and telephone numbers that are now obsolete. The following contact information is to be used instead:

- **While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration to the Restorative Devices Branch, 9200 Corporate Blvd., HFZ-410, Rockville, MD 20850.**
- **For questions regarding the use or interpretation of this guidance, contact the Restorative Devices Branch at 301-594-1296.**
- **To contact the Division of Small Manufacturers Assistance (DSMA), call 800-638-2041 or 301-443-6597; fax 301-443-8818; email dsma@cdrh.fda.gov; or write to DSMA (HFZ-200), Food and Drug Administration, 1350 Piccard Drive, Rockville, Maryland 20850-4307. FACTS-ON-DEMAND (800-899-0381 or 301-827-0111) and the World Wide Web (CDRH home page: <http://www.fda.gov/cdrh/index.html>) also provide easy access to the latest information and operating policies and procedures.**

I. INTRODUCTION

It is intended that this document be used in conjunction with the general information outlined in the "Draft - DCRND 510(k) Guidance" ([reference 4](#)). This document presents the 510(k) Premarket Notification requirements to be submitted in support of substantial equivalence to legally marketed cortical electrodes. For cortical electrodes that differ significantly from those currently on the market in either specification or intended use, FDA may require additional information specific to those differences.

II. BASIC DESIGN DESCRIPTION

Provide a complete description, in sufficient detail, of the device which will give the reviewer with a good understanding of the function and operation of your device. This description includes a pictorial representation of the major components, a representation illustrating implementation of the device and any other informative means of describing the function, manufacture, and operation of the device. Engineering drawings are required of the entire assembly and each component illustrating all dimensions and identifying all materials.

A legally marketed "predicate" device must be identified as part of the 510(k) process. Provide a comparison between the basic design features of your device and those of the predicate devices. The comparison should be presented in tabular form describing all features and characteristics of your device and the predicate device. Both similarities and differences between your device and the predicate device must be specified and described. Indicate the source of information you provide concerning the devices to which you are making a comparison; e.g., by specifying the number of a prior 510(k) from which you obtained data or by citing published data for preamendment devices.

III. DEVICE SPECIFICATIONS

The device specifications for cortical electrodes must be provided and include electrode lead materials, insulation material, nominal lead dimensions, electric current leakage, location of connections and attachment of electrodes.

Identify the electrodes used with your device specifying their contact material and provide data to support the safe and effective use of the electrodes with regard for their intended use. All devices found substantially equivalent to cortical electrodes have specified their electrode materials as either platinum or stainless steel for recording of electrical activity. All other materials used for the device must be supported with data demonstrating the safety and effectiveness of the electrode ([reference 5](#)). Silver electrodes implanted in the brain are known to have neurotoxic effects ([reference 1 and 2](#)) and we believe their use presents an unreasonable risk of injury. You must provide either evidence that your electrodes were legally marketed prior to May 28, 1976 or data which supports the safety and effectiveness of your electrodes for neurological use.

Specify any device that is required to operate or function in conjunction with your device and indicate if the device is under a Premarket Notification 510(k) number and provide the corresponding number.

A. SAFETY CONSIDERATIONS

Identify all materials that have contact with body tissue or body fluid and the duration of contact these materials have with use of your device. You must provide sufficient biocompatibility data to assure that all materials are reasonably safe and effective for their intended use. The Tripartite Biocompatibility Guidance document can provide some general guidelines for biocompatibility testing. All biocompatibility testing must be conducted on the final sterilized product and a sample size that is adequate to represent the intended use of the device. For each test performed you must provide a detailed test protocol including sample size justification, a clear description of the type of test sample, and an explanation of how applicable the sample is to the intended use of the device. Provide test results including the raw data, and a discussion of the test and the results.

Emphasis must be placed on protection of the patient when this device is connected with other electrical interface. What precautions have been provided to assure patient isolation. There must be data to assure that there is no direct current component and the patient is isolated from all potential faults during the operation of the system.

If the manufacturer intends to demonstrate substantial equivalence to a legally marketed predicate device in which their intended use is for electrical stimulation, substantially more information and data is required. Device labeling must specify the electrical output characteristics with which the device is compatible or otherwise specify the stimulation device with which safety and effectiveness can be assured.

B. PERFORMANCE TESTING AND QUALITY ASSURANCE TESTING

Describe all qualification and performance testing conducted on your device which supports a reasonable assurance of its safety and effectiveness. For each test performed you must provide a detailed test protocol including sample size justification, the test results including the raw data, and a discussion of the test and the results.

Provide a detailed description of your quality assurance procedures which assures a repeatable performance to specifications of your device.

C. STERILIZATION

You must specify whether your device is supplied sterile or non sterile. If your device is not supplied sterile you must specify this in your product labeling. If your device is supplied sterile you must provide the following ([reference 7](#)):

- 1) specify the sterilization method that will be used;

- 2) specify the sterility assurance level (SAL) for the device which the firm intends to meet;
- 3) describe the packaging used to maintain the device's sterility ([reference 3](#));
- 4) specify whether the product is labeled "pyrogen free" and a describe the method used to make that determination;
- 5) if sterilization employs ETO, specify the maximum levels of residues of ethylene oxide, ethylene chlorhydrin, and ethylene glycol which remain on the device;
- 6) if radiation sterilization is to be used, the radiation dose.

D. CLINICAL AND ANIMAL DATA

Providing any additional clinical data or animal data which supports the safety and effectiveness of the device for its specific intended use facilitates a substantial equivalence determination.

E. REFERENCE TO INDUSTRY STANDARDS

Reference to any applicable industry standards is helpful in which the manufacture and design of your device complies either in part or whole to provide additional support towards substantial equivalence to a predicate device.

IV. LABELING

Labeling and promotional material must be provided including complete instructions for use, package and product labeling, and any promotional material which describes the device's features, specifications, intended use, warnings, adverse effects and contraindications ([reference 6](#)).

Intended use (indications) for your device must clearly be stated in your labeling. Currently, all devices found substantially equivalent to the cortical electrode classification have only been labeled for short-term monitoring of cortical electrical activity during surgery. All other indications, such as, cortical electrodes intended for implantation, may be considered investigational. Specify whether the device is intended for recording or stimulation and if it is to be used pre-operatively or intraoperatively. For recording electrodes made of material that has not been proven safe for stimulation provide a contraindication for stimulation use. Specify how many electrodes can be placed simultaneously. Labeling must specify whether the device is intended for single use or multiple use, if it supplied sterile, and the shelf life.

V. REFERENCES

1. Casarett and Doull, Toxicology, Chapter 19, "Toxic Effects of Metals", 4th Edition, M.D. Amdur, J. Doull and C.D. Klaasen, Eds., Pergamon, New York, 1991.
2. M.J. Ellenhorn and D.G. Barceloux, Eds., Medical Toxicology: Diagnosis and Treatment of Human Poisoning, Chapter 37, "Metals and Related Compounds," Elsevier, New York, 1988.
3. Division of Cardiovascular, Respiratory, and Neurological Devices (DCRND) Red Book Memorandum, RB92-G, "Policy for Expiration Dating," October 1992.
4. Division of Cardiovascular, Respiratory, and Neurological Devices (DCRND) Draft Guidance, "DRAFT Guidance for Format and Content for Premarket Notification 510(k)," November 1993.
5. Office of Device Evaluation (ODE) General Program Memorandum, G87-1, "Tripartite Biocompatibility Guidance," April 1987.
6. Office of Device Evaluation (ODE) General Program Memorandum, G91-1, "Device Labeling Guidance," March 1991.
7. Office of Device Evaluation (ODE) Premarket Notification 510(k) Memorandum, K90-1, "510(k) Sterility Review Guidance," February 1990.