This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's

PREMARKET NOTIFICATION REVIEW GUIDANCE FOR EVOKED RESPONSE SOMATOSENSORY STIMULATORS

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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 General Surgical Devices Branch, 9200 Corporate Blvd., HFZ-410, Rockville, MD 20850.**
- **For questions regarding the use or interpretation of this guidance, contact the General Surgical Devices Branch at 301- 594-1307.**
- **To contact the Division of Small Manufacturers Assistance (DSMA), call 800-638-2041 or 301-443-6597; fax 301-443-8818; email dsmo@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.**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health
Rockville, MD 20850

I. Safe Electrical Design Criteria

A. Isolation. The manufacturer should specify the means by which isolation from commercial power and power line ground (return) is achieved. This may be determined by:

(1) Labeling that claims the device meets UL544.

(2) Employing battery operation. (Rechargeable batteries should be disconnected from the charger during use.)

(3) The use of an isolation transformer, or equivalent techniques, that provide fault protection by redundant insulation. (UL544 specifies several acceptable transformer designs for patient isolation.)

B. Leakage Current. The manufacturer must specify the level of leakage current through the patient connections. Also, verify whether or not leakage from the chassis of the device is excessive. Refer to the AAMI (draft) standard and UL544 as guides to acceptable levels, or compare with specific pre-enactment devices.

C. Applied Current Specification. The manufacturer should provide a detailed description of the electrical stimulus parameters. The stimulus parameters should be compared with those of the pre-enactment device. The device should include adequate instructions for use, including precautions that are needed to cope with the hazards of electrical stimulation.

(1) Pulse Width. Note that the pulse width need not exceed 0.6 milliseconds for a neural stimulation and much shorter pulses are generally used.

(2) Amplitude. Determine the peak current amplitude. If the device does not act as a constant-current source, assume a load impedance of 500 ohms and calculate the current from the output voltage. Using the current amplitude parameter, calculate the charge-per-pulse using:

$$q_p = \int_{rise}^{fall} i(t)\,dt$$

(3) Direct Current Decoupling. If the device is intended for stimulation of exposed nerve tissue, direct current must be avoided. The usual method is to apply the stimulus pulse through a capacitor which can discharge during the interpulse interval. If the device is not capacitively decoupled in this manner, determine whether or not there is a hazardous level of direct current.

II. Minimum Performance

A. Synchronization for Latency Measurement. The means by which the electrical output and evoked response recording are synchronized must be determined. If the stimulator provides a sync pulse to the computer (or other averaging device), determine the expected amount of jitter (relative time variation) between the sync

pulse and the stimulation event. If the computer provides a trigger pulse to the stimulator, determine the expected variability of the delay between the trigger and the stimulus output pulse. The amount of jitter must be compatible with the intended application.

B. Latency Measurement. The device must interface with the averaging device (computer) in a manner that allows accurate determination of the time relationship between the averaged evoked response and the stimulus. If the stimulator is being considered as a component of a larger system, determine whether the accuracy with which the overall system can measure latency. This accuracy must be compatible with the intended uses.

III. Intended Uses

The diagnostic capabilities of these pre-enactment devices were very limited, but many potential capabilities are under investigation. Any diagnostic claims which the manufacturer makes should be supported by conclusive clinical studies.

MANUFACTURERS NOTE :

Where specific guidance documents such as this one exist for your product, they should always be consulted. Current copies of these guidance documents may be obtained from Division of Small Manufacturers Assistance, CDRH, FDA, at 800-638-2041 or 301-443-6597, fax 301-443-8818.

Copies of all other guidance documents may be obtained from the Division of Small Manufacturers Assistance.