Neurometer® CPT

Sensory Nerve Conduction Threshold (sNCT®)
Electrodiagnostic Evaluation

Overview and References

Appendix J. FDA Labeling and other Notices

NEUROTRON, INCORPORATED
INNOVATIVE MEDICAL TECHNOLOGY
USA
www.neurotron.com

FDA Labeling

FDA permission to market the first sNCT/CPT device was granted on June 12, 1986. A copy of the notification is shown on the next page. Per FDA requirements, all sNCT equipment is classified as prescription devices. Federal law restricts it to sale by or on the order of a health care provider.

Potential Risks Associated with the sNCT Evaluation

The potential for adverse effects from an sNCT study are minimal because the procedure is non-invasive and the stimulus is provided by a battery. Since first coming to market in 1986, no serious adverse reactions to the studies have ever been reported. The electrode paste used to conduct the electrical stimulus is hypo-allergenic and water soluble. Although it is unlikely, there is a chance that a slight reddening of the skin may occur under the electrodes. If so, this will disappear within 30 minutes. Conducting this electrodiagnostic study directly over any implanted electrical device is contraindicated.

Physical Constraints on sNCT Study Sites

Electrode placement is contraindicated at any site where there are visible skin lesions or other signs recent trauma. Examination of test sites is a requirement prior to prescribing and performing sNCT studies. Placement of the electrodes at the site of a pacemaker, implanted spinal cord or peripheral nerve stimulator or other implanted devices is not recommended.

FDA Permission to Market Notice

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

JUN 12 1986

Food and Drug Administrat
8757 Georgia Avenue
Silver Spring MD 20910

Neurotron Incorporated
Medical Electronics
Attn: Jefferson J. Katims
6211 Falls Road
Baltimore, Maryland 21209

Re: K853608B
Neurometer
Dated: April 11, 1986
Received: April 17, 1986

Dear Mr. Katims:

We have reviewed your Section 510(k) notification of intent to market the above device and we have determined the device to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) until such time as your device has been classified under Section 513. At that time, if your device is classified into either class II (Performance Standards) or class III (Premarket Approval), it would be subject to additional controls. Please note: This action does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or regulations.

General controls presently include regulations on annual registration, listing of devices, good manufacturing practice, labeling, and the misbranding and adulteration provisions of the Act. In the future, the scope of general controls may be broadened to include additional regulations.

All regulations and information on meetings of the device advisory committees, their recommendations, and the final decisions of the Food and Drug Administration (FDA) will be published in the Federal Register. We suggest you subscribe to this publication so you can convey your views to FDA if you desire and be notified of any additional requirements imposed on your device. Subscriptions may be obtained from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Such information also may be reviewed in the Dockets Management Branch (HFA-305), Food and Drug Administration, Room 4-62, 5600 Fishers Lane, Rockville, Maryland 20857.

This letter does not in any way denote official FDA approval of your device or its labeling. Any representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding. If you desire advice on the labeling for your device or other information on your responsibilities under the Act, please contact the Office of Compliance, Division of Compliance Operations (HFZ-320), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Sincerely yours,

George C Murray

George C. Murray, Ph.D.
Director
Division of Anesthesiology, Neurology,
and Radiology Devices
Center for Devices and Radiological
Health

CC: Jefferson J. Katims
111 Lakeview Avenue
Valhalla, New York 10595