K991583

Section 3: Summary of Safety and Effectiveness

Neurosign 400 Motor Nerve Monitor

The Neurosign 400 is an EMG machine and nerve stimulator. The machine consists of a central control unit to which a pre-amplifier pod and intramuscular, or surface, electrodes are attached for EMG recordings. Additionally, connected to the main unit is a stimulator pod to which a stimulating probe, which delivers current to nerve tissue, may be connected.

The Neurosign 400 is intended to monitor and to stimulate cranial motor nerves. Cranial motor nerves are monitored by detecting EMG activity in the muscles they innervate.

The Neurosign 400 is similar to the following products which are currently in commercial distribution in the U.S.A.

Neurosign 800 Nerve Monitor, The Magstim Company, K964869
Neurosign 100 Nerve Monitor, The Magstim Company, K923056/A

The safety and effectiveness of the Neurosign 400 has been established through various techniques. The history of the similar products listed above lacks complaints related to safety and effectiveness, and as far as we are aware there have been no reports of adverse effects or reportable incidents connected with them, or in any published papers on nerve monitoring.

The Magstim Company performs extensive in-house an on-site clinical evaluation of all its products, both prior to, and after product release for distribution. Our methods and procedures for acceptance of products as well as our techniques for clinical evaluation are performed using team participation. Team members include, but are not limited to, Marketing, Manufacturing, Engineering and Quality Assurance. The Neurosign 400 has met all the specifications and expectations for its intended use based on the evaluations conducted thus far.

The materials and methods used to manufacture the Neurosign 400 do not vary from the current materials and methods used by the Magstim Company in the manufacture of the Neurosign 800. We will incorporate new, proven technologies as they become available; however, these improvements support product performance through greater reliability.

The Magstim Company concludes that the Neurosign 400 is safe and effective for its intended use. Clinical evidence in support of this statement is presented in Section 9 of this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 1999

Dr. Reza Jalinous
The Magstim Co. Ltd.
730 Fifth Ave., 9th Floor
New York, New York 10019

Re: K991583
Trade Name: Neurosign 400 Motor Nerve Monitor
Regulatory Class: II
Product Code: 77 ETN
Dated: April 29, 1999
Received: May 7, 1999

Dear Dr. Jalinous:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K991583

Device Name: Neurosign 400, 4 channel Motor Nerve Monitor

Indications For Use:

To locate and identify cranial motor nerves during ENT and intra-cranial procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K991583

Prescription Use: ✓ **OR** **Over-The-Counter Use:** _____
(Per 21 CFR 801.109)

Prescription Use _____
(Per 21 CFR 801.109)