K 021595

OCT 2 4 2002

510(k) Summary of Safety and Effectiveness

Trade Name:	Gyrus ENT Nerve Stimulator
Common Name:	Surgical nerve stimulator/locator
Classification Name:	Surgical nerve stimulator/locator (§ 874.1820)

Official Contact:	Gregory Sredin Sr. Regulatory Affairs Specialist Gyrus ENT LLC 2925 Appling Road Bartlett, TN 38133
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Date Prepared:	May 13, 2002

The Gyrus ENT Nerve Stimulator is intended to provide electrical stimulation to cranial and peripheral motor nerves to aid in nerve location during surgical procedures.

The Gyrus ENT Nerve Stimulator that is described in this notification has the same technological characteristics, power modality and mode of operation as the predicate device. The intended use is substantially equivalent to the described predicate Neurosign Model 100. The Gyrus ENT Nerve Stimulator is designed to meet:

- *UL2601/IEC 601 safety testing for 100Vac, 50/60 Hz.*
- *UL2601/IEC 601 safety testing for 120Vac, 50/60 Hz.*
- *UL2601/IEC 601 safety testing for 220Vac, 50/60 Hz.*
- *UL2601/IEC 601 safety testing for 240Vac, 50/60 Hz.*
- *EMC Testing, IEC 601-1-2.*

Conclusion: As a nerve stimulator only the Gyrus ENT Nerve Stimulator has the same intended use and the same basic technological characteristics as the Neurosign Model 100 Neural Tissue Stimulator and does not raise any new issues of safety or effectiveness.

Comparison Chart
Gyrus ENT Nerve Stimulator
vs.
Neurosign 100 Nerve Monitor

	Gyrus ENT Nerve Monitor	Neurosign 100 Nerve Monitor
Intended Use	The Gyrus ENT Nerve Stimulator is intended to provide electrical stimulation to the body to locate and identify nerves and to test their excitability.	The device is intended to stimulate and monitor cranial motor nerves.
Power Supply	100-240VAC; 50-60Hz, features power on LED.	100-240VAC; 50-60Hz
Frequency	3, 10, 30Hz, touch pad and frequency confirm indicator.	3, 30Hz, 2-position switch, no frequency confirm indicator.
Current	0.1 – 5.0 ma, in 0.1 ma increments with display to show setting and current confirm indicator.	0.15 – 5.0 ma, variable settings, but no display to show actual setting. Does feature current confirm indicator,
Probes supported	Monopolar and Bipolar	Monopolar and Bipolar

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 4 2002

Gyrus ENT
c/o Greg Sredin
Sr. Regulatory Affairs Specialist
2925 Appling Road
Bartlett, TN 38133

Re: K021595
Trade/Device Name: Gyrus ENT Nerve Stimulator
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/locator
Regulatory Class: Class II
Product Code: ETN
Dated: September 17, 2002
Received: September 18, 2002

Dear Mr. Sredin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

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

510(k) Number: K021595
Device Name: **Gyrus ENT Nerve Stimulator**

Indications for Use:

The Gyrus ENT Nerve Stimulator is intended to provide electrical stimulation to cranial and peripheral motor nerves to aid in nerve location during surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use C
(Per 21 CFR 801.109)

Prescription Use ✓ OR Over-the-Counter_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and [illegible]ses

510(k) Number K021595