K032115

510(k)
Summary of Safety and Effectiveness

Submitter:

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Date Prepared:

May 20, 2003

General Provisions:

Trade Name: Neurolac® Nerve guide

Common Name: Nerve guide

Classification Name: Nerve Cuff, 21 CFR 882.5275

Device Classification: Class II

Predicate Devices:

• Neurotube™	Neuroregen L.L.C.	K983007
• NeuroGen™	Integra Life Sciences Corp.	K011168

Performance Standards

For the Nerve Cuff performance, the FDA, under section 514 of the Food, Drug and Cosmetic Act, has not established standards.

Indications for Use

The Neurolac® nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

Device Description

Neurolac® is designed to be a flexible and transparent resorbable poly(DL-lactide-co-ε-caprolactone) tube to provide a protective environment for peripheral nerve regeneration after injury and to create a conduit to guide axonal growth across a nerve gap.

Neurolac® nerve guides are provided sterile in Tyvek pouch packages and retainer in a variety of sizes.

Performance Data:

The safety and effectiveness of the Neurolac nerve guides have been demonstrated via data collected from design verification tests and analyses. The design verification testing consisted of the following:

- In vitro suture retention testing
- In vitro degradation testing
- In vivo nerve function recovery

Summary of Substantial Equivalence

The design, fundamental technology and intended use (safety and efficacy) featured with the Neurolac® Nerve Guide are substantially equivalent to those featured with the competitor devices Neurotube™ (ref. 510(k) 983007; Neuroregen L.L.C.) and the NeuroGen™ Nerve Guide (ref. 510(k) 011168; Integra Life Sciences Corporation).

Biocompatibility, mechanical and physical property testing, in vitro degradation testing, and performance testing in an animal model provide reasonable scientific evidence that Neurolac® nerve guide is substantially equivalent to the predicate devices. Evaluation of the Polyganics Neurolac® Nerve guide based on biocompatibility testing, animal tests, results from literature and the comparison of the Neurolac® nerve guide with its predicate devices, shows that the Neurolac® nerve guide is safe for implantation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

Jan Bart Hak, Ph.D.
Manager, Clinical and Regulatory Affairs
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L.J. Zielstraweg 1
9713 GX, Groningen
The Netherlands

Re: K032115
Trade/Device Name: Neurolac® Nerve Guide
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve cuff
Regulatory Class: II
Product Code: JXI
Dated: July 3, 2003
Received: July 17, 2003

Dear Dr. Hak:

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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number: K032115

Device Name: **Neurolac® Nerve Guide**

Indications for Use:

The Neurolac nerve guide is indicated for the reconstruction of a peripheral nerve discontinuity up to 20 mm in patients who have sustained a complete division of a nerve.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

_____
(Division Sign-Off)

510(k) Number _____

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K032115