K050573 3/4

MAY - 4 2005

510(k)
Summary of Safety and Effectiveness

Submitter

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Contact Person

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Date Prepared

March 2, 2005

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

- Salumedica™ nerve cuff, Salumedica, K002098
- Neurogen™ nerve guide, Integra life science, K011168
- Neurolac® nerve guide, Polyganics BV, K032115

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® (4-10 mm) 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, for nerves with an internal diameter ≤ 9.5 mm, after injury and to create a conduit to guide axonal growth across a nerve gap.

Neurolac® (4-10mm) nerve guides are provided sterile in Tyvek pouch packages and retainer in a variety of sizes (4, 5, 6, 7, 8, 10 mm).

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 Neurogen™ nerve guide (ref. 510(k) 011168; Integra Life Science) and the Salumedica™ nerve cuff (ref. 510(k) 002098; Salumedica).

Biocompatibility, mechanical and chemical and physical property testing, in vitro degradation testing and performance testing, clinical testing and testing in an animal model provide scientific evidence that Neurolac (1-3 mm) nerve guide (510(k) 032115) is safe for implantation. Evaluation of the Polyganics Neurolac (4-10 mm) nerve guide based on results from literature and the comparison of the Neurolac (4-10 mm) nerve guide with its predicate devices, shows that the material of which the Neurolac (4-10mm) nerve guide is made, is safe for implantation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 4 2005

J.B. Hak, Ph.D.
Manager Clinical and Regulatory Affairs
Polyganics BV
L.J. Zielstraweg 1
NL-9713-GX Groningen
The Netherlands

Re: K050573
Trade/Device Name: Neurolac® nerve guide
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve cuff
Regulatory Class: II
Product Code: JXI
Dated: March2, 2005
Received: March 7, 2005

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 (240) 276-0115 . 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/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K050573

Indications for Use Form

510(k) Number: K050573

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.

Prescription Use____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K050573