3/22/99

K983007

PREMARKET NOTIFICATION [510(K)] SUMMARY
(as required by 21CFR 807.92(a))

Submitted by: John E. Barham, Managing Member, Neuroregen L.L.C.
43 N. Bond Street, Bel Air, MD 21014
Phone 410 838-8090 Fax 410 838-8092
Date: August 28, 1998

Trade Name: Neurotube[tm]

Common Name: Nerve Conduit

Classification Name: Nerve Cuff (per 21 CFR Section 882.5275)

Equivalent Device: Silicone Nerve Cuffs

Description: The Neurotube is a woven, flexible, polyglycolic acid tube which has been heat treated to achieve a configuration corrugated externally for wall strength. The tube is 2.3 mm in diameter and 4 cm in length.

Intended Use: The tube provides an optimal environment for longitudinal nerve axon growth of the peripheral nerve. For single use only in patients with a peripheral nerve injury where the nerve gap is more than or equal to 8 mm, but less than or equal to 3 cm.

Technological Characteristics Compared to Predicate Device: The Neurotube is fabricated from a bioresorbable material in contrast to nonresorbable silicone and thus precludes the need for a second surgery. Both the silicone and bioresorbable products are tubular in design to facilitate nerve regeneration.

Clinical Data: Clinical trials for the Neurotube were conducted in the United States over a period of three and one half years to support a determination of substantial equivalence.. A total of 98 subjects were enrolled at five clinical trial sites. One hundred two nerve reconstructions were evaluated. There were 56 in the control group using classic end-to-end nerve graft repairs and 46 received the Neurotube. Subjects were given sensory evaluations at 3, 6, 9, and 12 month intervals. Static and moving sensory discrimination tests were performed. Results were equivalent between the two groups. The only adverse effects reported were delayed healing of a skin closure and skin separation with partial extrusion of the Neurotube. The study indicated that a single stage, biodegradable, polyglycolic acid conduit can be used as an alternative to a nerve graft or a biodurable nerve tube.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 1999

Mr. John E. Barham
Managing Member
Neuroregen, L.L.C.
43 North Bond Street
Bel Air, Maryland 21014

Re: K983007
Trade Name: Neurotube™
Regulatory Class: II
Product Code: JXI
Dated: December 18, 1998
Received: December 22, 1998

Dear Mr. Barham:

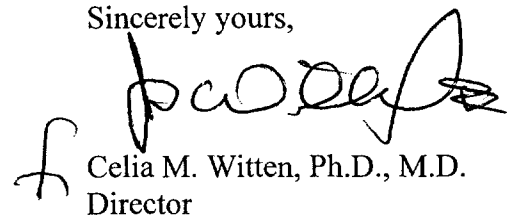
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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) 594-4595. 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,



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

Enclosure

K983007

510 (k) Number K983007

Device Name: Neurotube™

Indications for Use:

The Neurotube is intended for single use in patients with an injury to a peripheral nerve, in which the nerve gap is more than or equal to 8 mm but less than or equal to 3 cm. The nerve gap may be created primarily at the time of injury or created secondarily at the time of exploration of failed primary repair.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CRF 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983007