JUN 2 2 2001

NeuroGen™ Nerve Guide

510(K) SUMMARY

Submitter's name and address:

Integra LifeSciences Corporation
105 Morgan Lane
Plainsboro, NJ 08536 USA

Contact person and telephone number:

Judith E. O'Grady
Senior Vice President, Regulatory Affairs, Quality Assurance and Clinical Research
(609) 275-0500

Date Summary was prepared:

April 16, 2001

Name of the device:

Proprietary Name:	NeuroGen™
Common Name:	Nerve Guide
Classification Name:	Nerve Cuff, Product Code 84JXI

Substantial Equivalence:

NeuroGen™ Nerve Guide is substantially equivalent in function and intended use to the following products which have been cleared to market under Premarket Notifications 510(k): Salumedica™ Nerve Cuff, NeuroTube® and Fastube™ Nerve Cuff.

Device Description:

NeuroGen™ Nerve Guide is an implant designed for repair of peripheral nerve discontinuities. NeuroGen™ Nerve Guide provides a protective environment for peripheral nerve repair after injury. NeuroGen™ Nerve Guide is designed to be an interface between the nerve and surrounding tissue and to create a conduit for axonal growth across a nerve gap.

NeuroGen™ Nerve Guide is flexible to accommodate movement of joint and associated tendons while retaining its shape and is resistant to occlusive forces from surrounding tissue. When hydrated, NeuroGen™ is an easy to handle, soft, pliable, nonfriable, porous collagen tube. NeuroGen™ Nerve Guides are provided sterile in double blister packages in a variety of sizes.

Intended Use:

NeuroGen™ Nerve Guide is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

Safety

Biocompatibility studies have demonstrated NeuroGen™ Nerve Guides to be: noncytotoxic, nonpyrogenic, nonirritating, and nonsensitizing. The following studies were conducted:

a) Cytotoxicity
b) Irritation / Intracutaneous Reactivity
c) Sensitization
d) Acute Systemic Toxicity
e) Subchronic Toxicity
f) Chronic Toxicity
g) Genotoxicity
h) Implantation
i) Hemolysis

Performance Characteristics:

The effectiveness of NeuroGen™ Nerve Guide to repair peripheral nerve discontinuities was studied in a long-term (3.5 years) primate study and in rodent animal models. The studies demonstrated that NeuroGen™ Nerve Guides are substantially equivalent to nerve graft, direct suture and silicone tubes.

The mechanical and physical characteristics of the NeuroGen™ Nerve Guides were evaluated in a series of tests. These tests were conducted to ensure that the NeuroGen™ Nerve Guides possess the mechanical properties (suture retention and mechanical compression) as well as physical properties (porosity and permeability) that determine their suitability for use in the human body. Testing has demonstrated that the nerve guides are able to hold a suture, resist repeated compression from surrounding tissues, have a porous outer surface and tube wall, and allow the passage of molecules of specific size through the tube wall.

Technological Characteristics Compared to Predicate Devices:

NeuroGen™ Nerve Guide is a tubular device which is equivalent to the predicate devices, Salumedica™ Nerve Cuff, NeuroTube® and Fastube™ Nerve Cuff in its design for repair of peripheral nerve discontinuities. Like the predicate devices, NeuroGen™ is provided sterile, for single use only. The NeuroGen™ Nerve Guide is manufactured from a bioresorbable material, as is one of the predicate devices, NeuroTube®. NeuroGen™ Nerve Guide meets ISO 10993 requirements for Biocompatibility testing.

Conclusion

NeuroGen™ Nerve Guide is indicated for the repair of nerve discontinuities where gap closure can be achieved by flexion of the extremity. NeuroGen™ Nerve Guide is flexible to accommodate movement of joint and associated tendons while retaining its shape and is resistant to occlusive forces from surrounding tissue.

Biocompatibility studies have demonstrated NeuroGen™ Nerve Guide to be non-cytotoxic, non-sensitizing, non-toxic and non-mutagenic. Extensive, long-term evaluations in primates demonstrates NeuroGen™ Nerve Guide to biocompatible and provides an environment for axonal growth.

Valid scientific evidence through substantial testing of descriptive characteristics, Biocompatibility, mechanical and physical property testing and extensive performance testing in a primate model, provide reasonable assurance that NeuroGen™ Nerve Guide is safe and effective under the proposed conditions of use, and substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 2 2001

Ms. Judith E. O'Grady, RN, MSN
Senior Vice President, Regulatory Affairs,
Quality Assurance and Clinical Affairs
Integra Life Sciences Corporation
105 Morgan Lane
Plainsboro, New Jersey 08536

Re: K011168
Trade/Device Name: NeuroGen Nerve Guide
Regulation Number: 882.5275
Regulatory Class: II
Product Code: JXI
Dated: April 16, 2001
Received: April 17, 2001

Dear Ms. O'Grady:

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 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). 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) 594-4659. 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 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/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

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

510(k) Number: K011168

Device Name: NeuroGen™ Nerve Guide

Indications for Use

NeuroGen™ Nerve Guide is indicated for repair of peripheral nerve discontinuities where gap closure can be achieved by flexion of the extremity.

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

(Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use ____
(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011168