NeuraWrap™ Nerve Protector

510(K) SUMMARY

Submitter's name and address:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA

Contact person and telephone number:

Diana Bordon
Manager, Regulatory Affairs
Telephone: (609) 275-0500
Fax: (609) 275-9445

Date Summary was prepared:

June 14, 2004

Name of the device:

Proprietary Name:	NeuraWrap™
Common Name:	Nerve Protector
Classification Name:	Nerve Cuff (per 21 CFR section 882.5275)

Substantial Equivalence:

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

Device Description:

NeuraWrap™ nerve protector is an absorbable collagen implant that provides a non-constricting encasement for injured peripheral nerves for protection of the neural environment. NeuraWrap is designed to be an interface between the nerve and the surrounding tissue. When hydrated, NeuraWrap is an easy to handle, soft, pliable, nonfriable, porous collagen conduit. The wall of the conduit has a longitudinal slit that allows NeuraWrap to be spread open for easy placement over the injured nerve. The resilience of the collagen conduit allows NeuraWrap to recover and maintain closure once the device is placed around the nerve. NeuraWrap is provided sterile, non-pyrogenic, for single use only, in double peel packages in a variety of sizes.

Intended Use:

NeuraWrap™ Nerve Protector is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.

Testing and Test Results:

Biocompatibility studies have demonstrated NeuraWrap Nerve Protector to be non-cytotoxic, non-pyrogenic, non-irritating, non-sensitizing, non-toxic, non- genotoxic and non-hemolytic. Mechanical and physical testing demonstrate that NeuraWrap Nerve Protectors 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.

Conclusion

NeuraWrap™ Nerve Protector is safe and effective under the proposed conditions of use, and substantially equivalent to its predicate devices. Safety and efficacy are supported through physician experience with the equivalent NeuraGen product, testing of descriptive characteristics, biocompatibility, mechanical and physical property testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 16 2004

Ms. Diana Bordon
Manager, Regulatory Affairs
Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, New Jersey 08536

Re: K041620
Trade/Device Name: NeuraWrap™ Nerve Protector
Regulation Number: 21 CFR 882.5275
Regulation Name: Nerve cuff
Regulatory Class: II
Product Code: JXI
Dated: June 15, 2004
Received: June 16, 2004

Dear Ms. Bordon:

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.

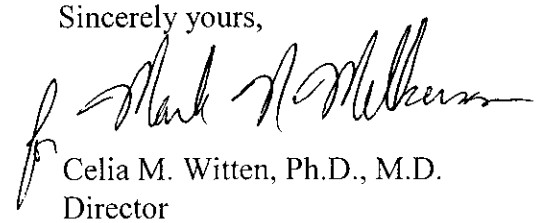
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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,



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

K041620

510(k) Number:

Device Name: NeuraWrap™ Nerve Protector

Indications for Use

NeuraWrap™ Nerve Protector is indicated for the management of peripheral nerve injuries in which there has been no substantial loss of nerve tissue.

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-the-Counter Use ____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041620