MAR 14 2006

1/1

510(k) SUMMARY

K053255

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

Submitter's Name: MicroSurgical Laboratories, dba Wexler Surgical Supplies
11333 Chimney Rock Road, Suite 110
Houston, TX 77035
Telephone: (713) 723-6900
Fax: (713) 723-6906
Contact person: Mr. Danny Fishman, COO

Date of Summary: February 17, 2006

Device Names:

Trade Name: Nexus Ligating Clips
Common Name: Titanium Hemostatic Clip
Classification Name: Implantable Clip (21 CFR 878.4300, Product Code FZP)

Legally Marketed Device to which Equivalence is Claimed: The legally marketed predicate devices are the Horizon Ligation Clips (K982313) manufactured by Weck Closure Systems, determined to be substantially equivalent to a legally marketed (preAmendment) device on August 10, 1998.

Device Description: The Nexus Ligating Clip is a titanium clip used during surgical procedures. The clips are supplied sterile in four sizes: small, medium, medium-large, and large; six clips per cartridge. The size of clip should be chosen based on experience, judgment, and needs, ensuring that the tissue to be occluded fits completely within the clip. The devices are heart-shaped to provide a firm grip on the structure to be ligated, and there are transverse grooves on the inner surface of each clip to resist slippage.

Intended Use: The Nexus Ligating Clip is indicated for use in surgical procedures on vessels or other tubular structures where a metal ligating clip is required.

Descriptive Summary of Technological Characteristics and Those of Predicate Device: The indications for use, principles of operation, and device design of the Nexus Ligating Clip are virtually identical to those of the predicate device. The Nexus devices are essentially a subset of the Horizon System, in that the Nexus Clip is offered in fewer sizes, only one cartridge capacity, and are made with titanium only, rather than titanium or tantalum. There are no significant differences in either technology nor performance specifications.

Performance Data: The sterilization cycle was validated in accordance with accepted international standards. Shelf life testing was performed to support the labeled shelf life period of five years. The results of all testing were within acceptable limits.

Conclusion: The information and data provided in this 510(k) Notification establish that the Nexus Ligating Clip is substantially equivalent to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 14 2006

MicroSurgical Laboratories, dba Wexler Surgical
Supplies
c/o Ms. Lisa S. Jones
Regulatory Affairs Consultant
Devices for the Future
540 College Street
Bellaire, Texas 77401

Re: K053255
Trade/Device Name: Nexus™ Ligating Clip
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: FZP
Dated: January 23, 2006
Received: January 24, 2006

Dear Ms. Jones:

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.

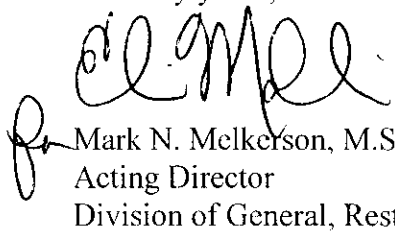
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



Mark N. Melkerson, M.S.
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K053255

WEXLER
SURGICAL SUPPLIES

Indications for Use

510(k) Number: K053255

Device Name: Nexus™ Ligating Clip

Indications for Use: The Nexus Ligating Clip is indicated for use in surgical procedures on vessels or other tubular structures where a metal ligating clip is required.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K053255

11333 Chimney Rock, Suite 110 Houston, Texas 77035 Phone: 713.723.6900 Toll Free: 800.414.1076
E-mail: sales@wexlersurgical.com Fax: 713.723.6906 www.wexlersurgical.com