K050969 1/2

AUG 1 8 2005

SECTION 2

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter:

Anulex Technologies, Inc.
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Contact Person:

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Date Prepared:

April 15, 2005

Trade Name:

Inclose™ Surgical Mesh System

Classification Name: and Number:

Surgical mesh, polymeric; 21CFR 878.3300

Product Code:

FTL

Predicate Device(s):

The Inclose™ Surgical Mesh System is substantially equivalent to:

Bard® Mesh PerFix® Plug
(K922916 - Decision Date: 8/24/1992)

Ethicon Mersilene Polyester Fiber Mesh
(K851086 – Decision Date: 5/21/1985)

Device Description:

The Inclose™ Surgical Mesh System is comprised of a Mesh Implant and two suture assembles (Anchor Bands). The implanted components are provided sterile and preloaded on their respective disposable delivery instruments. The Mesh Implant is an expandable braided patch that is inserted through the aperture of the tissue defect and affixed to surrounding soft tissue with the Anchor Bands. Materials utilized in the construct of the

	implanted components consist of polyethylene terephthalate (PET). In addition, two platinum/iridium markers are placed on monofilament fibers and positioned toward the proximal end of the mesh. These two markers are located 180° from each other and are intended to facilitate identification of the Inclose™ Mesh Implant following surgery. Standard operating room sutures may also be utilized for fixation of the device.
Intended Use:	The mesh may be used to support soft tissue where weakness exists, or for the repair of hernias requiring the addition of a reinforcing, or bridging material, such as the repair of groin hernias.
Functional and Safety Testing:	Biocompatibility and bench testing have been completed and support the safety and effectiveness of the Inclose™ Surgical Mesh System.
Conclusion:	The Inclose™ Surgical Mesh System is substantially equivalent in intended use, scientific technology, materials and design to predicate devices in interstate commerce.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2005

Mr. Tim Miller
VP, Regulatory and Clinical Affairs
Anulex Technologies, Inc.
5600 Rowland Road, Suite 280
Minnetonka, Minnesota 55343

Re: K050969
Trade/Device Name: Inclose™ Surgical Mesh System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: July 28, 2005
Received: July 29, 2005

Dear Mr. Miller:

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/dsma/dsmamain.html

Sincerely yours,

Marlene Brueh MD
for

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

Enclosure

K050969

INDICATIONS FOR USE

510(k) Number (if known): K050969

Device Name: Inclose™ Surgical Mesh System

Indications For Use:

The mesh may be used to support soft tissue where weakness exists, or for the repair of hernias requiring the addition of a reinforcing, or bridging material, such as the repair of groin hernias.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bye MD for Mel Kerson

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

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