K061386 1/1

Section 5 – 510(k) Summary

Submitter: Anulex Technologies, Inc.
5600 Rowland Road, Suite 280
Minnetonka, MN 55343

JUL - 5 2006

Contact Person: Tim Miller
Vice President, Regulatory and Clinical Affairs
Anulex Technologies, Inc.
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Date Prepared: May 17, 2006

Trade Name: Anchor Band Suturing System

Classification: II

Product Code: GAT
21 CFR 878.5000

Predicate Device(s): The subject device is substantially equivalent to the following predicate devices:

- ArthroCare Speedstitch
  (K042031 cleared October 19, 2004)
- AutoSuture SurgiStitch
  (K972911 cleared April 25, 1998)
- Teleflex Medical Polyester Nonabsorbable Suture
  (K021019 cleared June 18, 2002)

Device Description: The Anchor Band Suturing System consists of a non-absorbable braided surgical suture and T-anchor, both of which are composed of polyethylene terephthalate (PET). The suture, which conforms to U.S.P. 2-0, and T-anchor assembly are provided sterile and preloaded on a disposable delivery instrument. The instrument's needle facilitates placement of the suture by positioning the T-anchor in the sub-layer of the tissue.

Indications for Use: The Anchor Band Suturing System is indicated for use in soft tissue approximation for procedures such as general and orthopedic surgery.

Functional and Safety Testing: Biocompatibility and bench testing were completed and support the safety and effectiveness of the Anchor Band Suturing System.

Conclusion: The Anchor Band Suturing System is substantially equivalent in intended use, technological characteristics, materials and performance to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 5 2006

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

Re: K061386
Trade/Device Name: Anchor Band Suturing System
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: May 17, 2006
Received:, May 18, 2006

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K061386

Section 4 – Indications for Use Statement

Device Name: Anchor Band Suturing System

Indications for Use:

The Anchor Band Suturing System is indicated for use in soft tissue approximation for procedures such as general and orthopedic surgery.

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 K061386