K100572

Section 5 – 510(k) Summary

Applicant:	Anulex Technologies, Inc. 5600 Rowland Road, Suite 280 Minnetonka, MN 55343
Contact Person:	Rachel Kennedy Director of Regulatory and Quality Systems Telephone: 952.224.4034 Fax: 952.224.4040 e-mail: rkennedy@anulex.com
Date Prepared:	February 26, 2010
Trade Name:	Versaclose™
Product Classification and Code:	21 CFR §878.5000 Class: II Product Code: GAT
Predicate Device:	K061386 – Anchor Band Suturing System
Device Description:	The Versaclose implant is comprised of one (1) Peek Optima (LT1) Toggle-anchor, connected to an adjustable 2-0 braided suture loop, made of ultra high molecular weight polyethylene (UHMWPE) force fiber suture. The suture component conforms to USP requirements. The construct is provided sterile and preloaded on a disposable delivery instrument.
Intended Use:	Versaclose is indicated for use in soft tissue approximation for procedures such as general and orthopedic surgery.
Summary of Technological Characteristics:	The modifications to the Anchor Band Suturing System were conducted in accordance with the Anulex Design Control System. Accordingly, the risk analysis identified necessary design verification and validation activities. As a result of this analysis, tensile testing was performed to confirm compliance to USP suture requirements.
Conclusion:	The modified Anchor Band Suturing System (Versaclose) is substantially equivalent to the original Anchor Band Suturing System in regards to the indications for use, technology and the basic operating principle.

MAR 17 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Anulex Technologies, Inc.
% Ms. Rachel Kennedy
Director of Regulatory & Quality Systems
5600 Rowland Road, Suite 280
Minnetonka, Minnesota 553430

MAR 17 2010

Re: K100572
Trade/Device Name: Versaclose™
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable poly(ethylene terephthalate) surgical suture
Regulatory Class: II
Product Code: GAT
Dated: February 26, 2010
Received: March 1, 2010

Dear Ms. Kennedy:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Peter D. Pfendler

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

Enclosure

Indications for Use

510(k) Number (if known): K100572

Device Name:

Versaclose™ is indicated for use in soft tissue approximation for procedures such as general and orthopedic surgery.

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)

Daniel Krone for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100572