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Section 5 – 510(k) Summary

DEC 19 2008

Submitter: Anulex Technologies, Inc.
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Date Prepared: September 15, 2008

Trade Name: Rimclose Bone Anchor

Classification: II

Product Code: MBI
21 CFR 888.3040

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

- Arthrex Small Bone FASTak™ Suture Anchor (K971723 cleared July 30, 1997)

Device Description: The Rimclose Bone Anchor consists of one (1) bone anchor assembly, pre-loaded on a disposable delivery tool. The Bone Anchor is packaged with a disposable Bone Awl to facilitate placement of the device. The device is provided in one size only.

The bone anchor assembly is comprised of one (1) titanium (Ti-6Al-4V ELI) toggle-anchor, connected to an adjustable polyethylene terephthalate (PET) 2-0 braided suture loop, via an intermittent length of size 0 ultra high molecular weight polyethylene (UHMWPE) Force Fiber suture.

The device's titanium component conforms to ASTM F-136. The device's polyethylene terephthalate (PET) and ultra high molecular weight polyethylene (UHMWPE) suture components conform to USP requirements. The constructs are provided sterile and preloaded on disposable delivery instruments.

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Indications for Use:

The Rimclose Bone Anchor is intended for fixation of suture to bone. This product is intended for the following indications:

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction

Functional and Safety Testing:

Biocompatibility and bench testing were completed and support the safety and effectiveness of the Rimclose Bone Anchor.

Conclusion:

The Rimclose Bone Anchor is substantially equivalent to the Arthrex FASTak Suture Anchor (7.5mm). In this case, substantial equivalence is based on having the same intended use with minor differences in technological characteristics, such that it can be demonstrated that the device is as safe and effective as the predicate device. Both anchors are both made of titanium. FASTak uses threads for fixation in bone while the Rimclose anchor is a T-anchor which toggles on deployment. Both anchors are provided with suture to facilitate attachment to soft tissue. The bone anchors demonstrated equivalent fixation strength which greatly exceeded the tensile strength of the suture. USP performance characteristics serve as a guide in matching suture to procedural applications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Anulex Technologies, Inc.
% Ms. Rachel Kennedy
Senior Regulatory Affairs Manager
5600 Rowland Road, Suite 280
Minnetonka, Minnesota 55343

DEC 19 2008

Re: K082729
Trade/Device Name: Rimclose Bone Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: December 18, 2008
Received: December 19, 2008

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Section 4 – Indications for Use Statement

Device Name: Rimclose Bone Anchor

Indications for Use:

The Rimclose Bone Anchor is intended for fixation of suture to bone. This product is intended for the following indications:

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

David Krause for MXM 12/19/2008

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

510(k) Number K082729