Appendix 5: 510(k) Summary

K121354

As Required by 21 CFR 807.92

NOV 9 2012

Submitter:	Anulex Technologies, Inc. 5600 Rowland Road, Suite 280 Minnetonka, MN 55343
Contact Person:	Rachel Kennedy Director, Regulatory Affairs and Quality Systems Anulex Technologies, Inc. Direct: 952.224.4034 Fax: 952.224.5417 E-Mail: rkennedy@anulex.com
Date Prepared:	October 25, 2012
Trade Name:	Micro/Mini N-PK(F) Bone Anchor
Classification:	II
Product Code:	MBI 21 CFR 888.3040
Predicate Device(s):	The subject device is substantially equivalent to the following predicate devices: • Smith & Nephew, Inc., Bioraptor PK Suture Anchor (K071586 cleared August 17, 2007) • DePuy Mitek Mini QuickAnchor Plus (K071257 cleared June 29, 2007)
Device Description:	The Micro/Mini N-PK(F) Bone Anchor consists of an adjustable loop of non-absorbable suture (Sizes 2, 0 and 2-0) with one (1) or two (2) attached anchors. The bone anchor is a two part system, one part nickel-titanium (nitinol) and the second part polyetheretherketone (PEEK). The PEEK part resides within the nitinol sleeve and retains the suture. The nitinol part expands upon delivery providing resistance to pullout. The construct is provided sterile and preloaded on a disposable delivery instrument.
Indications for Use:	The Micro/Mini N-PK Bone Anchor is intended for the reattachment of soft tissue to bone for the following indications: **Foot and Ankle** • Hallux valgus repairs

	• Medial or lateral instability repairs/reconstructions • Achilles tendon repairs/reconstructions • Midfoot reconstructions • Metatarsal ligament/tendon repairs/reconstructions • Bunionectomy
Functional and Safety Testing:	Biocompatibility testing was conducted in accordance with ISO 10993-1 standards. Corrosion testing was conducted in accordance with ASTM F2129. Tensile testing was performed to verify compliance with USP suture requirements and comparison testing to support the safety and effectiveness of the Micro/Mini N-PK(F) Bone Anchor included evaluation of fixation/static disassembly strength and cyclic fatigue performance.
Comparison to Predicate:	The Micro/Mini N-PK(F) Bone Anchor that is the subject of this submission has the same materials and similar technological characteristics in comparison to the predicate suture anchors. The intended use is the same as the predicates, fixation of soft tissue to bone for a variety of orthopedic procedures in the foot and ankle while the predicate anchors include procedures in additional anatomical locations.
Conclusion:	Substantial equivalence is demonstrated through the detailed device description, performance testing and conformance with voluntary performance standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Letter Dated: November 9, 2012

Anulex Technologies, Incorporated
% Ms. Rachel Kennedy
Director, Regulatory Affairs and Quality Systems
5600 Rowland Road, Suite 280
Minnetonka, Minnesota 55343

Re: K121354
Trade/Device Name: Micro/Mini N-(PK)(F) Bone Anchor
Regulation Number: 21 CFR 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener.
Regulatory Class: Class II
Product Code: MBI
Dated: October 26, 2012
Received: October 31, 2012

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,

Mark N. Melkerson

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

Enclosure

K121354

Appendix 4: Indications for Use Form

Device Name: Micro/Mini N-PK(F) Bone Anchor

Indications for Use:

The Micro/Mini N-PK Bone Anchor is intended for the reattachment of soft tissue to bone for the following indications:

Foot and Ankle

- Hallux valgus repairs
- Medial or lateral instability repairs/reconstructions
- Achilles tendon repairs/reconstructions
- Midfoot reconstructions
- Metatarsal ligament/tendon repairs/reconstructions
- Bunionectomy

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K121354