510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
(Per 21 CFR 807.92)

General Company Information

Name: Anchor Innovation Medical, Inc.

Contact: Howard Schrayer
Regulatory Consultant

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Date Prepared October 7, 2013

OCT 16 2013

General Device Information

Product Name: A.I.M.™ Suture Anchor

Classification: "Non-degradable soft tissue fixation fastener"
Product code: MBI - Class II

Predicate Device

Smith & Nephew, Inc.	Bioraptor™ 2.3 PK Suture Anchor. [510(k) Number K071586]
Mitek, Inc..	MiniLok Quick Anchor Plus™ Suture Anchor [510(k) K030995]

Description

The implant system includes a 1.7mm diameter PEEK (polyether-etherketone) anchor, pre-mounted on a disposable inserter. The anchor is preloaded with USP size 0 Ultra High Molecular Weight Polyethylene suture. The device is designed to be inserted into a pre-formed hole using a single use disposable awl

Intended Use (Indications)

The A.I.M.™ Suture Anchor is intended for use in arthroscopic, mini-open or open surgical procedures for fixation of soft tissue to bone.

The A.I.M.™ Suture Anchor is intended for use in the following applications:

- **Ankle:** Mid-foot Reconstruction
- **Foot:** Hallux valgus reconstruction
- **Hand:** Ulnar or lateral collateral ligament reconstruction
- **Wrist**: Scapholunate ligament reconstruction

Substantial Equivalence

This submission supports the position that the A.I.M.™ Suture Anchor is substantially equivalent to previously cleared devices, including those listed above. Data have been provided in the submission that demonstrates that the anchor pull-out forces are equivalent or superior to a referenced predicate device. Biocompatibility of the anchor was established through reference to data on file from the provider of the PEEK material. The referenced predicate devices include the same range of clinical uses in their labeling.

Conclusions

Anchor Innovation Medical, Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same clinical applications as the A.I.M.™ Suture Anchor. The materials from which the Anchor Innovation Medical device is fabricated have an established history of use, and the devices have been tested in accordance with applicable FDA guidelines. The A.I.M.™ Suture Anchor is substantially equivalent to previously marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 16, 2013

Anchor Innovation Medical, Incorporation
Mr. Howard Schrayer
Regulatory Consultant
5410 Edson Lane, Suite 308
Rockville, Maryland 20852

Re: K132461
Trade/Device Name: A.I.M.™ Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: August 28, 2013
Received: August 29, 2013

Dear Mr. Schrayer:

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 contact 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. 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 Erin D Keith

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K132461

Device Name: A.I.M.™ Suture Anchor

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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)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices