510(k) Summary

JAN 30 2014

Device Trade Name: Titanium Suture Anchor

Manufacturer:
MTP Solutions LLC
124 South 600 West, Suite 100
Logan, UT 84321

Contact:
Mr. Robert Hoy
Director of Technical & Clinical Research
Phone: (614) 448-6358
Fax: (435) 213-4878
bob@venturemd.com

Prepared by:
Musculoskeletal Clinical & Regulatory Advisers, LLC
1331 H Street NW, 12th Floor
Washington, DC 20005
Phone: (202) 552-5800
Fax: (202) 552-5798

Date Prepared: October 18, 2013

Common Name: Fastener, Fixation, Soft Tissue

Classification: 21 CFR 888.3040

Class: II

Product Codes: MBI

Indications for Use:
The Titanium Suture Anchor is intended to be used for suture or tissue fixation in the foot, ankle, knee, hip, hand, wrist, elbow and shoulder. Specific indications are listed below:

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hip: Capsular repair, acetabular labral repair

Device Description:
The Titanium Suture Anchor is a titanium alloy threaded device designed to attach soft tissues to bone when used in conjunction with suture.

Predicate Device:
The Titanium Suture Anchor is substantially equivalent to the Arthrex Tak (K050749 & K061863) with respect to its indications for use, design, function, and performance.

Technological Characteristics Comparison:
The Titanium Suture Anchor and its predicate device are similar in size and shape. Both devices are generally cylindrical and have features on their outer diameter for engaging bone tunnel walls. In addition both devices are designed to be deployed in conjunction with suture. The Titanium Suture Anchor is manufactured from titanium alloy and the predicate is manufactured from one of two resorbable polymers. This material difference does not raise any new issues of safety or effectiveness. There are no substantial differences in technological characteristics between the two devices and as such the Titanium Suture Anchor introduces no new issues of safety or effectiveness.

Nonclinical Testing:
All necessary testing has been performed for the Titanium Suture Anchor to assure substantial equivalence to the predicate device and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. Clinical data was not needed to support the safety and effectiveness of the subject device.

The device design was qualified through the following tests:

- Simulated Use Testing
- Axial Insertion Force Testing
- Ultimate Strength Testing

Conclusion:
The Titanium Suture Anchor met all specified criteria and did not raise new safety or performance questions. The Indication/Intended Use and the fundamental scientific technology of the Titanium Suture Anchor are the same as those described in the predicate device. The Titanium Suture Anchor is determined by MTP Solutions to be substantially equivalent to the Arthrex Tak (K050749 & K061863).

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

January 30, 2014

MTP Solutions LLC
Mr. Robert Hoy
Director of Technical & Clinical Research
124 South 600 West, Suite 100
Logan, Utah 84321

Re: K133229
Trade/Device Name: Titanium 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: December 16, 2013
Received: December 17, 2013

Dear Mr. Hoy:

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" (21 CFR 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,

Vincent J. Devlin -S

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

Enclosure

4. Indications for Use

510(k) Number (if known): K133229

Device Name: Titanium Suture Anchor

Indications for Use:

The Titanium Suture Anchor is intended to be used for suture or tissue fixation in the foot, ankle, knee, hip, hand, wrist, elbow and shoulder. Specific indications are listed below:

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Shoulder: Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Hand/Wrist: Scapholunate Ligament Reconstruction, Carpal Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction

Knee: Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Hip: Capsular repair, acetabular labral repair

Prescription Use √ (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) Page 1 of 1

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices