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

General Company Information

Name: Tornier, Inc.
Contact: Howard Schrayer
Regulatory Affairs Consultant

FEB 12 2009

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Date Prepared November 4, 2008

General Device Information

Product Name: Insite™ Suture anchors

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

Predicate Devices

Original 510(k) Notice	Anchor Material	Nominal Anchor Size (Diameter)	Date Cleared
K003971	Titanium	3mm	March 21, 2001
K011912	Titanium	5mm	August 31, 2001
K052491	Titanium	6.5mm	October 7, 2005
K051983	PLLA Polymer	3mm	August 5, 2005
K041698	PLLA Polymer	5mm	October 5, 2004
K151250	PLLA Polymer	6.5mm	June 9, 2005
K060970	Acetal Polymer	3, 5 and 6.5mm	July 5, 2006

Description

The devices described in this 510(k) Notice are exactly the same device as the predicate Axya Medical Suture anchors described in the 510(k) Notices listed above. The various anchors are fabricated from titanium, PLLA absorbable polymer and acetal polymer. They are provided in diameters of 3mm, 5mm and 6.5mm to facilitate the attachment of soft tissue to bone.

No changes have been made to the devices.

Intended Use (Indications)

Tornier® Insite™ Bioabsorbable Suture Anchors are intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder: Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulabral reconstruction

Foot/Ankle: Lateral and Medial stabilization, Achilles tendon and Metatarsal ligament repair, Hallux Valgus and Midfoot reconstruction,

Knee: Medial collateral and Lateral collateral ligament repair, Patellar tendon and Posterior oblique ligament repair. Illiotibial band tenodesis

Hand/Wrist: Scapholunate ligament Radial collateral ligament and Ulnar collateral ligament reconstruction

Elbow: Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction

Pelvis: Bladder neck suspension for urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency

Substantial Equivalence

This submission supports the position that the Tornier Insite™ Suture anchors are substantially equivalent to the previously cleared Axya Medical devices listed above.

Conclusions

Tornier, Inc. believes that the information provided establishes that similar legally marketed devices have been used for the same range of clinical applications as the Tornier Insite™ Suture anchors. The materials from which the Tornier devices are fabricated have an established history of use, and the devices have been tested in accordance with applicable FDA guidelines.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Tornier, Inc.
C/o Mr. Howard Schrayer
Regulatory Affairs Consultant
100 Cummings Center
Beverly, MA 01915

FEB 12 2009

Re: K083268
Trade/Device Name: Insite™ Suture anchors
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, MBI
Dated: November 4, 2008
Received: November 18, 2008

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.

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 Biometrics' (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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K083268

Device Name: Insite™ Suture Anchors

Indications For Use:

Tornier® Insite™ Suture Anchors are intended for use for the reattachment of soft tissue to bone for the following indications:

Shoulder: Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulabral reconstruction
Foot/Ankle: Lateral and Medial stabilization, Achilles tendon and Metatarsal ligament repair, Hallux Valgus and Midfoot reconstruction
Knee: Medial collateral and Lateral collateral ligament repair, Patellar tendon and Posterior oblique ligament repair, Iliotibial band tenodesis
Hand/Wrist: Scapholunate ligament, Radial collateral ligament and Ulnar collateral ligament reconstruction
Elbow: Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction
Pelvis: Bladder neck suspension for urinary incontinence due to urethral hypermobility or intrinsic sphincter deficiency in females

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)

Mark N Milhous

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

510(k) Number K083268