APR 04 2014

SECTION 5: 510(K) PREMARKET NOTIFICATION

510(k) Summary of Safety and Effectiveness Information

Tornier, Inc. Insite FT PEEK Knotless Suture Anchor

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1. Device name

Device name:	Tornier Insite™ FT PEEK Knotless Suture Anchor
Device:	Suture anchor
Classification name:	Smooth or threaded metallic bone fixation fastener
Classification number:	21 CFR § 888.3030; 888.3040
Product code:	MBI – Fastener, Fixation, Nondegradable, Soft Tissue

2. Submitter

Tornier Inc.
10801 Nesbitt Avenue South
Bloomington, MN 55437
Registration Number: 9100540

3. Company contact

Mireille Lemery
Tornier Inc.
10801 Nesbitt Avenue South
Bloomington, MN 55437
Phone: +33 4 76 61 38 98
Fax: +33 4 76 61 35 65
Email: mireille.lemery@tornier.com

4. Classification

Device class: Class II

Classification panel: Orthopedic

Product code: MBI

5. Legally Marketed Device to which Equivalence is Claimed:

The Tornier Insite FT PEEK Knotless Suture Anchor is substantially equivalent in intended use and fundamental scientific technology to the following legally marketed device in commercial distribution: Tornier, Inc. Insite FT Suture Anchor, K110773 and RõG Sports Medicine Knotless Anchor, K110230.

6. Device Description

The Tornier Insite FT PEEK Knotless Suture Anchor is a bone implant device intended for the fixation of soft tissue to bone. This device is a fully threaded PEEK-OPTIMA® anchor

that is available in three sizes (4.5mm, 5.5mm, and 6.5mm) for use in a range of fixation applications. The device is assembled pre-loaded onto the insertion device and may be used with specific USP Size #2 sutures.

The Tornier Insite FT PEEK Knotless Suture Anchor is individually packaged and sterilized through ethylene oxide (EO) using appropriate standards and guidelines.

7. Materials

The Tornier Insite FT PEEK Knotless Suture Anchor is available in PEEK-OPTIMA® material.

8. Indications for Use

The Tornier Insite FT PEEK Knotless Suture Anchors are intended for fixation of soft tissue to bone.

The Tornier Insite FT PEEK Knotless Suture Anchors are intended for use in the following applications:

1. Shoulder: Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulolabral reconstruction.
2. Foot/Ankle: Lateral and Medial stabilization, Achilles tendon and Metatarsal ligament repair, Hallux Valgus and Midfoot reconstruction.
3. Knee: Medial collateral and Lateral collateral ligament repair, Patellar tendon and Posterior oblique ligament repair, Illiotibial band tenodesis.
4. Hand/Wrist: Scapholunate ligament, Radial collateral ligament and Ulnar collateral ligament reconstruction.
5. Elbow: Biceps tendon reattachment, Tennis elbow repair, Ulnar and Radial collateral ligament reconstruction.

9. Summary of Technologies

The technological characteristics (material, design, sizing, indications, sterilization, and fixation strength) of the Tornier Insite FT PEEK Knotless Suture Anchors are similar or identical to the cited predicate devices.

10. Nonclinical Testing

Non-clinical laboratory testing and assessments were performed; these are: mechanical insertion and fixation strength, as compared to the predicate devices, for the specific indications for use. The results of these tests indicate that the Tornier Insite FT PEEK Knotless Suture Anchor is substantially equivalent in performance and efficacy to the above cited predicate devices within their intended use.

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

April 4, 2014

Tornier, Incorporated
Ms. Mireille Lemery
Director, Global Regulatory Affairs
10801 Nesbitt Avenue South
Bloomington, Minnesota 55437

Re: K133777
Trade/Device Name: Insite™ FT PEEK Knotless 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: January 2, 2014
Received: January 7, 2014

Dear Ms. Lemery:

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,

Ronald P. Jean -S for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133777

Device Name
Insite PT PEEK Knotless Suture Anchor

Indications for Use *(Describe)*

The Tornier Insite FT PEEK Knotless Suture Anchors are intended for fixation of soft tissue to bone.
The Tornier Insite FT PEEK Knotless Suture Anchors are intended for use in the following applications:
1. Shoulder: Rotator Cuff, Bankart and SLAP lesion repair, Biceps tenodesis, Acromio-Clavicular separation and Deltoid repair, Capsular shift and Capsulolabral reconstruction.
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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