



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

Tornier, Incorporated
Ms. Kaitlyn Rainbow
Sr. Regulatory Affairs Specialist
10801 Nesbitt Avenue South
Bloomington, Minnesota 55437

July 28, 2015

Re: K150715

Trade/Device Name: 2.5mm Insite Ft Suture Anchors , 3.5mm Insite Ft Suture Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI
Dated: June 19, 2015
Received: June 22, 2015

Dear Ms. Rainbow:

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 Industry and Consumer Education 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 Industry and Consumer Education 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 -S

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

Indications for Use

510(k) Number (if known)

K150715

Device Name

2.5mm & 3.5mm Insite™ FT PEEK Suture Anchor

Indications for Use (Describe)

Intended Use:

The 2.5mm and 3.5mm Insite™ FT PEEK Suture Anchor is intended for total shoulder arthroplasty of the shoulder.

Indications for Use:

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

The Tornier Insite™ FT PEEK 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, Iliotibial 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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Traditional Premarket Notification 510(k)
2.5mm & 3.5mm Insite™ FT PEEK Suture Anchors
Tornier, Inc.

510(k) Summary

Date Prepared: July 24, 2015

I. Administrative Information

Name: Tornier, Inc.
Address: 10801 Nesbitt Avenue South
Bloomington, MN 55437
Contact Person: Kaitlyn Rainbow
Senior Regulatory Affairs Specialist
Phone: 952-426-7637
Fax: 952-426-7601

II. Device Information

Name of Device: Insite™ FT PEEK Suture Anchor Size 2.5mm & 3.5mm
Common Name: Fastener, Fixation, Non-degradable, Soft Tissue
Classification Name: 21 CFR 888.3040, Smooth or treaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI

III. Predicate Device Information

Tornier Insite™ FT PEEK Knotless Suture Anchor K110773 and Smith and Nephew 2.0PK Suture Anchor K081511.

IV. Device Description

The Insite™ FT PEEK 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 two sizes (2.5mm & 3.5mm) for use in a range of fixation applications.

V. Intended Use

The Tornier Insite™ FT PEEK Suture Anchor is intended for the fixation of soft tissue to bone.

VI. Indications for Use

The Tornier Insite FT PEEK 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:

Traditional Premarket Notification 510(k)
2.5mm & 3.5mm Insite™ FT PEEK Suture Anchors
Tornier, Inc.

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.

This device is for single use.

VII. Comparison of Technological Characteristics with the Predicate Device

The Insite™ FT Suture Anchor has the same intended use and fundamental scientific technology as the predicate device. The design differences have been demonstrated to not affect safety or effectiveness or raise new issues of safety or effectiveness.

VIII. Performance Data

Non-clinical performance bench testing (mechanical testing) was performed to demonstrate substantial equivalence to the predicate devices.

Non-clinical Performance Testing Summary for 2.5mm & 3.5mm Insite™ FT PEEK Suture Anchors

Validation and/ or Verification Method	Acceptance Value/Criteria	Verification and Validation Results
Mechanical Testing (Suture Approximation and Tensile Pull-out)	To exceed strength of predicate device	Acceptable
Mechanical Testing (Cyclic Load Test)	To meet the physiological loading requirements	Acceptable
Mechanical Testing (Anchor Insertion Torque and Driver Torque to Failure Test)	To exceed the strength of the expected loading requirements	Acceptable
Mechanical Testing (Pull to Failure Testing)	To determine strength of predicate device	Acceptable
Cadaver Lab Evaluation	Successful preparation in cadaveric specimens	Acceptable

IX. Clinical Study

Clinical studies were not required to demonstrate substantial equivalence between the subject device and the predicate device.

X. Conclusions

The Insite™ FT Suture Anchor size 2.5mm and 3.5mm described in this section has the same intended use and the same fundamental scientific technology as the cleared Insite™ FT Suture Anchor and Smith and Nephew 2.0PK Suture Anchor. Based on the testing presented for the design differences between the subject and predicate devices, Tornier concludes that subject device is substantially equivalent to the predicate device.