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

August 4, 2015

Tornier, Incorporated
Brian Hockett
Director of Research and Development- Lower Extremity
1065 Medina Road, Suite 500
Medina, Ohio 44256

Re: K150871
Trade/Device Name: ForeFoot STP System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: July 2, 2015
Received: July 6, 2015

Dear Mr. Hockett:

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

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 below.

510(k) Number *(if known)*
K150871

Device Name
ForeFoot STP System

Indications for Use *(Describe)*

The Tornier ForeFoot STP Screw System is indicated for fixation of fractures, fusions, and osteotomies of bones of the hand and foot.

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.

510(k) SUMMARY

Submitter Information

Submitter's Name:	Tornier, Inc.
Address:	1065 Medina Rd, Suite 500 Medina, Ohio 44256
Telephone Number:	330-869-9562
Fax Number:	330-247-1598
Prepared By:	Liz Altenau, Andy Leither
Contact Person:	Brian Hockett
Date Prepared:	3/12/2015

Device Information

Trade Name:	ForeFoot STP System
Common Name:	Fixation Screws
Classification Name:	Screw, Fixation, Bone
Device Classification:	Smooth or threaded metallic bone fixation fastener Class II per 21 CFR 888.3040 Panel: Orthopedic, Product Code: HWC
Material Composition:	Titanium Alloy
Primary Predicate Device:	Vilex/Duval/Orthex Cannulated Bone Screw Double Thread, K014154
Additional Predicate Devices:	SBI AutoFix System, K052576 OrthoHelix MaxTorque System, K131324 Nexa Bone Screw System, K053394
Device Description:	The submission is regarding the ForeFoot STP System. This system consists of screws of various diameters, lengths and thread configurations.
Indications for Use:	The Tornier ForeFoot STP Screw System is indicated for fixation of fractures, fusions, and osteotomies of bones of the hand and foot.
Substantial Equivalence:	The Tornier ForeFoot STP screws are substantially equivalent to the previously cleared predicate devices. Cross-sectional bending analysis and mechanical axial pull-out testing comparing the strength of the subject and predicate devices was performed and the results support substantial equivalence. Mechanical testing was completed to ensure that the torsional strength, insertion torque, and removal torque are appropriate for the potential applications of the device. Due to similarities in indications, design, and materials, no other testing was required; therefore, the subject device was demonstrated to be as safe and effective as the above predicates.