Tornier, Inc.
Lisa Stahl
Principal Specialist, Regulatory Affairs
10801 Nesbitt Ave South
Bloomington, Minnesota 55437

October 31, 2023

Re: K230352
Trade/Device Name: Tornier Humeral Nail and Tornier Long Humeral Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: September 21, 2023
Received: September 22, 2023

Dear Lisa Stahl:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Farzana Sharmin -S

Digitally signed by Farzana Sharmin -S
Date: 2023.10.31 17:33:57 -04'00'

Farzana Sharmin, Ph.D.
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K230352

Device Name

Tornier Humeral Nail and Tornier Long Humeral Nail

Indications for Use *(Describe)*

The Tornier Humeral Nail System is intended to provide temporary stabilization of various types of proximal and/or diaphyseal fractures of the humerus. Types of fractures include, but are not limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures. Examples of specific indications according to AO classification include Type A-Fractures, dislocated, Type B Fractures, dislocated, Type C-Fractures, with intact humeral head, or Humeral Fractures according to Neer-Classification (2, 3 and 4 part fractures).

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."

Date Prepared: October 31, 2023

Administrative Information

Name:	Tornier, Inc.
Address:	10801 Nesbitt Avenue South Bloomington, MN 55437 United States of America
Contact Person:	Lisa Stahl
Title:	Principal Specialist, Regulatory Affairs
Phone:	612-849-9970
Email:	lisa.stahl@stryker.com

Device Information

Name of Device:	Tornier Humeral Nail and Tornier Long Humeral Nail
Common Name(s):	Intramedullary Fixation Rod
Regulatory Class:	II
Regulation:	21 CFR 888.3020
Product Codes:	HSB

Predicate Device Information

Predicate:	Aequalis® Humeral Nail System
510(k) Number:	K133376

Device Description

The Tornier Humeral Nail and Tornier Long Humeral Nail include intramedullary nails and screws. The Tornier Humeral Nail is a straight, cannulated intramedullary nail available in 9mm proximal diameter with a tapered 7mm distal diameter with nail lengths of 210mm, 230mm, 250mm, and 270mm long and a tapered 8mm distal diameter with nail lengths of 130mm, 210mm, 230mm, 250mm, and 270mm long. Both distal diameter sizes are available in right and left configurations. The proximal end of the nail contains screw holes in four axes for proximal locking using 5mm cannulated screws. The proximal end of the nail also contains a cannulated polyethylene insert with screw holes aligned with those of the nail. This insert is intended to help prevent the proximal screws from backing out. The distal end of the 130mm nails incorporate two or three screw holes for distal stabilization using 4.3mm screws. The nails and screws are manufactured from anodized titanium alloy. The polyethylene insert is manufactured from ultra-high molecular weight polyethylene (UHMWPE).

Indications for Use

The Tornier Humeral Nail System is intended to provide temporary stabilization of various types of proximal and/or diaphyseal fractures of the humerus. Types of fractures include, but are not

limited to, non-unions, malunions, malalignments, pathological fractures, and impending pathological fractures. Examples of specific indications according to AO classification include Type A-Fractures, dislocated, Type B Fractures, dislocated, Type C-Fractures, with intact humeral head, or Humeral Fractures according to Neer-Classification (2, 3 and 4 part fractures).

Comparison of Technological Characteristics with the Predicate Device

There have been no changes to the technological characteristics of the Tornier Humeral Nail and Tornier Long Humeral Nail as a result of the revision to the labeling to add MR conditional language. The subject devices have the same design and are manufactured from the same materials as the predicate devices.

Non-clinical Performance Testing

The Tornier Humeral Nail and Tornier Long Humeral Nail has been evaluated in a Magnetic Resonance Environment through non-clinical testing as outlined in the FDA guidance document "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment – Guidance for Industry and FDA Staff", dated October 10, 2023. This testing was conducted to characterize the compatibility of the Tornier Humeral Nail System in the MR environment.

Clinical Testing

No clinical studies were performed.

Conclusion

The Tornier Humeral Nail System does not raise different questions of safety or effectiveness. Based upon a comparison of the intended use, materials, summary of technological characteristics, and non-clinical evaluation, the subject Tornier Humeral Nail and Tornier Long Humeral Nail is considered substantially equivalent to the current Tornier Humeral Nail and Tornier Humeral Long Nail (cleared as Aequalis Humeral Nail System on K133376).