October 28, 2026

Tornier, Inc.
Rachel Zigler
Staff Regulatory Affairs Specialist
10801 Nesbitt Ave. S.
Bloomington, Minnesota 55441

Re: K263583
Trade/Device Name: Tornier Humeral Reconstruction System (HRS) Tuberosity Body
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, HSD, PHX
Dated: September 30, 2026
Received: September 30, 2026

Dear Rachel Zigler:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

JOSEPH P. RUSSELL -S

for: Farzana Sharmin, PhD
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K263583

Please provide the device trade name(s).

Tornier Humeral Reconstruction System (HRS) Tuberosity Body

Please provide your Indications for Use below.

In Anatomic
The Tornier HRS is to be used only in patients with an intact or reconstructable rotator cuff, where it is intended to provide increased mobility and stability and to relieve pain. The Tornier HRS is indicated for use as a replacement of shoulder joints disabled by:
• Rheumatoid arthritis with pain
• Non-inflammatory degenerative joint disease (i.e., osteoarthritis and avascular necrosis)
• Correction of functional deformity
• Fractures of the humeral head
• Traumatic arthritis
• Revision of other devices if sufficient bone stock remains.

In Reverse
The Tornier HRS is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle with pain disabled by:
• Rheumatoid arthritis
• Non-inflammatory degenerative joint disease (i.e., osteoarthritis and avascular necrosis)
• Correction of functional deformity
• Fractures of the humeral head
• Traumatic arthritis
• Massive and non-repairable rotator cuff tear
• Revision of other devices if sufficient bone stock remains.
The reversed tray and polyethylene insert are indicated for use in the conversion from an anatomic to reversed shoulder arthroplasty without the removal of the humeral assembly during revision surgery for patients with a functional deltoid muscle

Notice
• All components are single use.
• The coated humeral stem is intended for cemented or cementless use.
• The all-poly glenoid components are intended for cemented use only.
• The glenoid sphere implant is anchored to the bone with screws and is for noncemented fixation.
• Titanium humeral heads are intended for patients with suspected cobalt alloy material sensitivity. The wear properties of titanium and titanium alloys are inferior to that of cobalt alloy. A titanium humeral head is not recommended for patients who lack a suspected material sensitivity to cobalt alloy.

Please select the types of uses.

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

Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

510(k) #:

510(k) Summary

Prepared on: 2026-09-30

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Tornier, Inc.
Applicant Address	10801 Nesbitt Avenue South Bloomington MN 55441 United States
Applicant Contact Telephone	574-371-6155
Applicant Contact	Ms. Rachel Zigler
Applicant Contact Email	rachel.zigler@stryker.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Tornier Humeral Reconstruction System (Tornier HRS) Tuberosity Body
Common Name	Shoulder joint metal/polymer semi-constrained cemented prosthesis
Classification Name	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
Regulation Number	888.3660
Product Code(s)	KWS, HSD, PHX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K241878	Tornier Humeral Reconstruction System (Tornier HRS)	KWS, PHX, H
K251686	Tornier Humeral Reconstruction System Max (Tornier HRS Max)	KWT, KWS, H

Device Description Summary

21 CFR 807.92(a)(4)

The Tornier HRS Tuberosity Body (subject device) is a modular humeral implant component that can be used as an alternative to the Tornier HRS Proximal Body (predicate device). It is intended for use only with compatible Tornier HRS components and provides a reconstruction option when the proximal humerus and associated tuberosity or soft-tissue attachments require restoration. The device utilizes the established Tornier HRS screw connection and allows the humeral construct to be completed in either an anatomic configuration with a compatible humeral head or a reverse configuration. Proximally, the Tuberosity Body connects to a compatible humeral head or reversed tray; distally, it connects directly to a compatible Tornier HRS stem or to the stem through one or more compatible HRS spacers.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

In Anatomic
The Tornier HRS is to be used only in patients with an intact or reconstructable rotator cuff, where it is intended to provide increased mobility and stability and to relieve pain. The Tornier HRS is indicated for use as a replacement of shoulder joints disabled by:

- Rheumatoid arthritis with pain
- Non-inflammatory degenerative joint disease (i.e., osteoarthritis and avascular necrosis)
- Correction of functional deformity
- Fractures of the humeral head
- Traumatic arthritis
- Revision of other devices if sufficient bone stock remains.

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The Tornier HRS is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle with pain disabled by:
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• All components are single use.
• The coated humeral stem is intended for cemented or cementless use.
• The all-poly glenoid components are intended for cemented use only.
• The glenoid sphere implant is anchored to the bone with screws and is for noncemented fixation.
• Titanium humeral heads are intended for patients with suspected cobalt alloy material sensitivity. The wear properties of titanium and titanium alloys are inferior to that of cobalt alloy. A titanium humeral head is not recommended for patients who lack a suspected material sensitivity to cobalt alloy.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The Tornier HRS Tuberosity Body has the same Indications for Use as the Tornier HRS Proximal Body (K241878).

Technological Comparison 21 CFR 807.92(a)(6)

The subject Tornier HRS Tuberosity Bodies have the same intended use, principle of operation and similar techological features as the predicate Tornier HRS Proximal Bodies. Differences between the Proximal Body and Tuberosity Body are dimensional and do not introduce new intended use, princple of operation or techological features to Tornier HRS.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

No additional testing was generated as a result of the addition of the Tornier HRS Tuberosity Body to Tornier HRS. Previous device testing for predicate device HRS and reference device HRS Max was assessed for applicability to the HRS Tuberosity Body and provided in summary format. Differences between the subject device and the predicate device are dimensional and do not introduce new questions of safety and effectiveness. Therefore, the Tornier HRS Tuberosity Body is substantially equivalent to the Tornier HRS Proximal Body.