October 30, 2025

Tornier, Inc.
Stefanie Tarara
Principal Regulatory Affairs Specialist
10801 Nesbitt Avenue South
Bloomington, Minnesota 55441

Re: K251686
Trade/Device Name: Tornier Humeral Reconstruction System Max (Tornier HRS Max)
Regulation Number: 21 CFR 888.3650
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWT, KWS, HSD, PHX
Dated: October 2, 2025
Received: October 3, 2025

Dear Stefanie Tarara:

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.

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 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: 2025.10.30 18:07:56 -04'00'

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.	K251686

Please provide the device trade name(s).

Tornier Humeral Reconstruction System Max (Tornier HRS Max)

Please provide your Indications for Use below.

In Anatomic:
Tornier HRS Max humeral assembly can be used for anatomic arthroplasty when used with a humeral head. It can be used as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with a glenoid, as a total replacement.

Tornier HRS Max is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with an intact or reconstructable rotator cuff with pain disabled by:
• Rheumatoid arthritis
• Non-inflammatory degenerative joint disease (i.e., osteoarthritis and avascular necrosis)
• Fractures of the humeral head
• Post-Traumatic arthritis
• Oncology applications including bone loss due to tumor resection
• Significant humeral resection where adequate fixation can be achieved

In Reverse:
Tornier HRS Max is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with massive and non-repairable rotator cuff-tear 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
• Post-Traumatic arthritis
• Massive and non-repairable rotator cuff tear
• Oncology applications including bone loss due to tumor resection.
• Significant humeral resection where adequate fixation can be achieved

The reversed tray and polyethylene insert are indicated for use in the conversion from an anatomic to reversed shoulder arthroplasty without the removal of a well-fixed 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 non-cemented 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 (select one or both, as applicable).

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

510(k) #:

510(k) Summary

Prepared on: 2025-10-30

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	1-269-800-2754
Applicant Contact	Mrs. Stefanie Tarara
Applicant Contact Email	stefanie.tarara@stryker.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Tornier Humeral Reconstruction System Max (Tornier HRS Max)
Common Name	Shoulder joint metal/polymer non-constrained cemented prosthesis
Classification Name	Prosthesis, Shoulder, Non-Constrained, Metal/Polymer Cemented
Regulation Number	888.3650
Product Code(s)	KWT, KWS, HSD, PHX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K223631	Comprehensive Segmental Revision System (SRS)	KWT
K241878	Tornier Humeral Reconstruction System (Tornier HRS); Tornier Perform Humeral System -Stem (Tornier PHS - Stem)	KWS

Device Description Summary

21 CFR 807.92(a)(4)

The HRS Max System is designed to address massive proximal humeral bone loss and provide for deltoid wrapping. The modular functionality of the HRS Max Shoulder System allows clinicians to create constructs that address unique anatomies which include proximal humeral bone loss, while also allowing for use in anatomic, hemiarthroplasty or reversed configuration.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

In Anatomic:
Tornier HRS Max humeral assembly can be used for anatomic arthroplasty when used with a humeral head. It can be used as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with a glenoid, as a total replacement.

Tornier HRS Max is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with an intact or reconstructable rotator cuff with pain disabled by:

- Rheumatoid arthritis
- Non-inflammatory degenerative joint disease (i.e., osteoarthritis and avascular necrosis)
- Fractures of the humeral head
- Post-Traumatic arthritis
- Oncology applications including bone loss due to tumor resection
- Significant humeral resection where adequate fixation can be achieved

In Reverse:
Tornier HRS Max is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle and with massive and non-repairable rotator cuff-tear 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
- Post-Traumatic arthritis
- Massive and non-repairable rotator cuff tear
- Oncology applications including bone loss due to tumor resection.
- Significant humeral resection where adequate fixation can be achieved

The reversed tray and polyethylene insert are indicated for use in the conversion from an anatomic to reversed shoulder arthroplasty without the removal of a well-fixed 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 non-cemented 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)

TThe Tornier HRS Max System indications for use align with those of the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

Tornier HRS Max and the predicate Comprehensive Segmental Revision System (SRS) have the same intended use, similar principle of operation and technological features. The differences for the subject Tornier HRS Max include multiple sized proximal bodies for deltoid wrapping.

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

Non-clinical testing was performed to demonstrate substantial equivalence to the predicate device.
- Fatigue testing with corrosion evaluation
- Pull out and torque out testing
- Range of motion testing
- Biocompatibility evaluation
- Packaging and shelf-life evaluations
- Sterilization evaluation
- Endotoxin testing
- MRI compatibility evaluation

No clinical studies were performed.

The Tornier HRS Max does not raise new questions of safety or effectiveness and has been shown to be substantially equivalent to the predicate device.