Stryker Corporation (Tornier, Inc.)
Jang Long
Staff Specialist, Regulatory Affairs
10801 Nesbitt Avenue South
Bloomington, Minnesota 55437

September 10, 2024

Re: K241609
Trade/Device Name: Tornier Humeral Reconstruction System (Tornier HRS)
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, PHX, HSD
Dated: August 9, 2024
Received: August 9, 2024

Dear Jang Long:

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,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2024.09.10 11:11:10 -04'00'

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241609

Device Name

Tornier Humeral Reconstruction System (Tornier HRS)

Indications for Use *(Describe)*

IN ANATOMIC:
The proximal body, stem, assembly screw, locking cap, optional spacer(s), and humeral head may be used together, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement.

The Tornier HRS Shoulder System 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 Shoulder System 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 Shoulder System 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 the 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.

Notes:
- 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.

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.

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510(k) #: K241609

510(k) Summary

Prepared on: 2024-09-09

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Stryker Corporation (Tornier, Inc.)
Applicant Address	10801 Nesbitt Avenue South Bloomington MN 55437 United States
Applicant Contact Telephone	612-258-5639
Applicant Contact	Ms. Long Jang
Applicant Contact Email	jang.long@stryker.com
Correspondent Name	Stryker Corporation (Tornier, Inc.)
Correspondent Address	10801 Nesbitt Avenue South Bloomington MN 55437 United States
Correspondent Contact Telephone	612-258-5639
Correspondent Contact	Ms. Jang Long
Correspondent Contact Email	jang.long@stryker.com

Device Name

21 CFR 807.92(a)(2)

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

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K191318	Aequalis Flex Revive Shoulder System Line Extension	KWS,PHX,HSD
K181420	Aequalis Flex Revive Shoulder System	KWS,PHX,HSD

Device Description Summary

21 CFR 807.92(a)(4)

Tornier HRS (formerly branded Aequalis™ Flex Revive™ Shoulder System) is a fully convertible anatomic and reversed shoulder arthroplasty system that is designed to be used with existing Tornier implant systems. It is a non-constrained system intended for total or partial replacement of the glenohumeral articulation. Tornier HRS includes a proximal body (metaphysis), spacer(s), a stem, assembly screw, and locking cap. The proximal body has a female taper that is compatible with Tornier Flex (formerly branded Ascend Flex) Humeral Heads and Tornier Flex (formerly branded Ascend Flex) reversed trays and poly inserts.

Tornier HRS is implanted by a surgeon and is designed to allow the surgeon to select the components to size the shoulder system for the patient. It allows the shoulder to be constructed in an anatomical or reversed configuration using cleared Tornier Flex (formerly branded

Ascend Flex) Humeral Heads and Tornier Flex (formerly branded Ascend Flex) reversed trays and inserts. In addition, Tornier HRS can be transformed from anatomic to reverse shoulder prosthesis without the removal of the humeral implant assembly during revision surgery.
The humeral length is measured to determine the overall humeral implant construct length. The length is assembled from 120 mm (using the short proximal body and stem) to 300 mm (using the standard proximal body, spacers, and stem) in 10 mm increments with the spacers as needed and either of the two available lengths of the proximal body for patient specificity.
The proximal body, stem, and spacers are made from Ti6Al4V per ASTM F-136. The proximal body and stem have a Titanium plasma spray coating. The assembly screw and locking cap are made of CoCr per ISO 5832-12. All implant parts are single use and packaged sterile, using gamma radiation at a minimum dose of 25 kGy to an SAL of 1x10-6.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

IN ANATOMIC:
The proximal body, stem, assembly screw, locking cap, optional spacer(s), and humeral head may be used together, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement.

The Tornier HRS Shoulder System 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 Shoulder System 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 Shoulder System 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 the 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.

Notes:
- 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)

The indications for use of the subject and predicate devices are identical. There is no impact to the indications for use as a result of the revision to the labeling to add MR conditional safety information. Therefore, adding Magnetic Resonance (MR) Conditional Labeling does not raise different questions of safety or effectiveness.

Technological Comparison

21 CFR 807.92(a)(6)

Based upon a comparison of the intended use, materials, summary of technological characteristics, and non-clinical evaluation, the

subject Tornier HRS is substantially equivalent to the current Tornier HRS (cleared as Aequalis Flex Revive in K191318 and K181420). There have been no changes to the technological characteristics of Tornier HRS as a result of the revision to the labeling to add MR conditional safety information. The subject devices have the same design and are manufactured from the same materials as the predicate devices.

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

The Tornier HRS system 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 Tornier HRS in the MR environment.

No clinical studies were performed.

The Tornier HRS 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 HRS is considered substantially equivalent to the current Tornier HRS (cleared as Aequalis Flex Revive in K191318 and K181420).