Tornier, Inc.
Renee Stoffel
Principal Specialist, Regulatory Affairs
10801 Nesbitt Ave South
Bloomington, Minnesota 55437

October 14, 2022

Re: K220914
Trade/Device Name: Tornier Perform Humeral System - Fracture
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PAO, HSD, KWS, KWT, PHX
Dated: October 5, 2022
Received: October 5, 2022

Dear Renee Stoffel:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Victoria Lilling, M.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)*

K220914

Device Name
Tornier Perform® Humeral System - Fracture

Indications for Use *(Describe)*

In Anatomic:
The Tornier Perform Humeral System – Fracture combined with a humeral head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with a glenoid implant, as a total replacement.

The Tornier Perform Humeral System – Fracture is to be used only in patients with an intact or reconstructable rotator cuff, where it is intended to provide increased mobility, stability, and to relieve pain.

The Tornier Perform Humeral System – Fracture is indicated for use as a replacement of shoulder joints disabled by:
• Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures
• Fracture sequelae
• Revisions where adequate fixation can be achieved and adequate bone stock remains after final reconstruction

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 without a suspected material sensitivity to cobalt alloy.

All components are single use. The fracture stems are intended for cemented or cementless use. In cementless use, the fracture stems are intended for use with or without cortical screws. In a total shoulder arthroplasty, the Tornier Perform Humeral System – Fracture is intended to be used with cemented polyethylene glenoid components.

In Reverse:
The Tornier Perform Humeral System – Fracture combined with a reverse insert is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle, grossly deficient rotator cuff, and pain disabled by:
• Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures
• Proximal humerus bone defect
• Fracture sequelae
• Revisions where adequate fixation can be achieved and adequate bone stock remains after final reconstruction

The reversed insert is indicated for use for the conversion from an anatomic to reverse shoulder prosthesis without the removal of a well fixed fracture stem for patients with a functional deltoid muscle.

All components are single use. The fracture stems are intended for cemented or cementless use. In cementless use, the fracture stems are intended for use with or without cortical screws. The Tornier Perform Humeral System – Fracture is intended to be used with glenoid implants that are anchored to the bone with screws for non-cemented fixation.

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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Date Prepared: October 5, 2022

Administrative Information

Name:	Tornier, Inc.
Address:	10801 Nesbitt Avenue South Bloomington, MN 55437 United States of America
Contact Person:	Renee Stoffel
Title:	Principal Specialist, Regulatory Affairs
Phone:	952-683-7471
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Device Information

Name of Device:	Tornier Perform® Humeral System – Fracture
Common Name (s):	Shoulder Prosthesis
Regulatory Class:	II
Regulation:	21 CFR 888.3660, Shoulder joint metal/polymer semi-constrained cemented prosthesis. 21 CFR 888.3650, Shoulder joint metal/polymer non-constrained cemented prosthesis. 21 CFR 888.3690, Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
Product Codes:	PHX, KWS, KWT, HSD, PAO

Predicate Device Information

Primary Predicate:	Aequalis Reversed Fracture Shoulder Prosthesis and Aequalis Shoulder Fracture System, K131231
Reference Device:	Humelock Reversed Shoulder, K162455
Reference Device:	Perform Humeral System – Stem, K201315

Device Description

The Tornier Perform Humeral System – Fracture is a convertible humeral fracture system for anatomic, reverse, and hemiarthroplasty of the shoulder. The system also allows for conversion from an anatomic to a reverse shoulder prosthesis in the case of revision. The Tornier Perform Humeral System – Fracture is implanted with existing Tornier glenoid systems for total anatomic and reverse shoulder arthroplasty.

The Tornier Perform Humeral System – Fracture includes titanium fracture stems, titanium couplers, titanium spacers and titanium screws. The system is compatible with commercially available Perform humeral heads and reversed inserts. The system also includes reusable instruments used to implant the shoulder prosthesis.

Indications for Use

In Anatomic:

The Tornier Perform Humeral System – Fracture combined with a humeral head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with a glenoid implant, as a total replacement.

The Tornier Perform Humeral System – Fracture is to be used only in patients with an intact or reconstructable rotator cuff, where it is intended to provide increased mobility, stability, and to relieve pain.

The Tornier Perform Humeral System – Fracture is indicated for use as a replacement of shoulder joints disabled by:

- Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures
- Fracture sequelae
- Revisions where adequate fixation can be achieved and adequate bone stock remains after final reconstruction

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 without a suspected material sensitivity to cobalt alloy.

All components are single use. The fracture stems are intended for cemented or cementless use. In cementless use, the fracture stems are intended for use with or without cortical screws. In a total shoulder arthroplasty, the Tornier Perform Humeral System – Fracture is intended to be used with cemented polyethylene glenoid components.

In Reverse:

The Tornier Perform Humeral System – Fracture combined with a reverse insert is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle, grossly deficient rotator cuff, and pain disabled by:

- Traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures
- Proximal humerus bone defect
- Fracture sequelae
- Revisions where adequate fixation can be achieved and adequate bone stock remains after final reconstruction

The reversed insert is indicated for use for the conversion from an anatomic to reverse shoulder prosthesis without the removal of a well fixed fracture stem for patients with a functional deltoid muscle.

All components are single use. The fracture stems are intended for cemented or cementless use. In cementless use, the fracture stems are intended for use with or without cortical screws. The Tornier Perform Humeral System – Fracture is intended to be used with glenoid implants that are anchored to the bone with screws for non-cemented fixation.

Comparison to Predicate Devices

The Tornier Perform Humeral System – Fracture and the predicate, Aequalis Reversed Fracture Shoulder Prosthesis and Aequalis Shoulder Fracture System (K131231), have the same intended use, same principle of operation, and similar technological features. Differences for the subject Tornier Perform Humeral System – Fracture include the stem coating material, compatibility with Perform humeral heads and reversed inserts, and the option to implant the stem with cortical screws.

Non-clinical Performance Testing

Non-clinical testing was performed to demonstrate substantial equivalence to the predicate devices.

- Fatigue testing
- Static taper evaluation
- ASTM F543 screw testing
- Evaluations for compatibility with existing components
- Range of motion analysis
- MRI compatibility evaluation

Biocompatibility, sterilization, cleaning, endotoxin, packaging, shelf life, and distribution for the Tornier Perform Humeral System – Fracture components were also assessed in accordance with recognized consensus standards.

Clinical Testing

No clinical studies were performed.

Conclusions

The Tornier Perform Humeral System – Fracture does not raise different questions of safety or effectiveness. Differences in technological characteristics have been addressed with performance testing. The results of performance testing for the Tornier Perform Humeral System – Fracture support substantial equivalence to the predicate Aequalis Reversed Fracture Shoulder Prosthesis and Aequalis Shoulder Fracture System (K131231).