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

September 11, 2020

Re: K201315
Trade/Device Name: PERFORM Humeral System - Stem
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PAO, KWT, KWS, HSD, PHX
Dated: August 7, 2020
Received: August 12, 2020

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,

For Michael Owens
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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K201315

Device Name
PERFORM™ Humeral System – Stem

Indications for Use *(Describe)*

In Anatomic:
The humeral stem, humeral head coupler and 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 PERFORM™ Humeral System – Stem 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 PERFORM Humeral System – Stem is indicated for use as a replacement of shoulder joints disabled by:
• Non-inflammatory degenerative joint disease (i.e. osteoarthritis) and avascular necrosis
• Correction of functional deformity
• Post-traumatic arthritis
• Revisions or fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains

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 humeral stems are intended for cemented or cementless use.

The PERFORM Humeral System – Stem is intended to be used with cemented polyethylene glenoid components, in a total shoulder arthroplasty.

In Reverse:
The PERFORM™ Humeral System – Stem is indicated for use as a replacement of a shoulder joint for patients with a functional deltoid muscle, grossly deficient rotator cuff, and pain disabled by one or more of the following:
• Non-inflammatory degenerative joint disease (i.e. osteoarthritis) and avascular necrosis
• Pseudoparalysis or anterior superior escape
• Rotator cuff tear arthropathy
• Correction of functional deformity
• Post-traumatic arthritis
• Revisions or fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains

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

All components are single use. The humeral stems are intended for cemented or cementless use. The PERFORM Humeral System – Stem 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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*"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: August 7, 2020

## Administrative Information


| | |
|---|---|
| Name: | Tornier, Inc. |
| Address: | 10801 Nesbitt Avenue South<br>Bloomington, MN 55437<br>United States of America |
| Contact Person: | Renee Stoffel |
| Title: | Principal Regulatory Affairs Specialist |
| Phone: | 952-683-7471 |
| Fax: | 952-426-7601 |


## Device Information

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

## Predicate Device Information

| | |
|---|---|
| Predicate: | AEQUALIS ASCEND™ FLEX Shoulder System |
| 510(k) Number: | K190521 |
| Reference Device: | AEQUALIS™ REVERSED Shoulder System |
| 510(k) Number: | K151293 |

## Device Description

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

The PERFORM Humeral System – Stem includes titanium humeral stems, cobalt chrome and titanium humeral heads, titanium humeral head couplers, conventional and Vitamin E UHMWPE reversed inserts, and titanium humeral spacers. The system also includes reusable instruments used to implant the shoulder prosthesis.

## Indications for Use

**In Anatomic:**

The humeral stem, humeral head coupler and 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 PERFORM™ Humeral System – Stem 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 PERFORM Humeral System – Stem is indicated for use as a replacement of shoulder joints disabled by:

- Non-inflammatory degenerative joint disease (i.e. osteoarthritis) and avascular necrosis
- Correction of functional deformity
- Post-traumatic arthritis
- Revisions or fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains

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 humeral stems are intended for cemented or cementless use.

The PERFORM Humeral System – Stem is intended to be used with cemented polyethylene glenoid components, in a total shoulder arthroplasty.

**In Reverse:**

The PERFORM™ Humeral System – Stem is indicated for use as a replacement of a shoulder joint for patients with a functional deltoid muscle, grossly deficient rotator cuff, and pain disabled by one or more of the following:

- Non-inflammatory degenerative joint disease (i.e. osteoarthritis) and avascular necrosis
- Pseudoparalysis or anterior superior escape
- Rotator cuff tear arthropathy
- Correction of functional deformity
- Post-traumatic arthritis
- Revisions or fractures of the humeral head where adequate fixation can be achieved and adequate bone stock remains

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

All components are single use. The humeral stems are intended for cemented or cementless use. The PERFORM Humeral System – Stem is intended to be used with glenoid implants that are anchored to the bone with screws for non-cemented fixation.

## Comparison to Predicate Device

The PERFORM Humeral System – Stem and the predicate AEQUALIS ASCEND FLEX Shoulder System have the same intended use, same principle of operation, and similar technological features. Differences for the subject PERFORM Humeral System – Stem include humeral stems with a modified connection mechanism, modular humeral heads, Vitamin E UHMWPE reverse inserts, and an optional humeral spacer instead of a required humeral tray.

## Non-clinical Performance Testing

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

- Fatigue testing
- Static taper evaluation to ASTM F2009
- Static Reversed Insert testing
- Wear and range of motion evaluations
- Vitamin E material characterization testing
- MRI compatibility evaluation
- Biocompatibility evaluation to ISO 10993-1
- Packaging and shelf life evaluations to ISO 11607-1, ISO 11607-2, ASTM F1980
- Distribution testing to ISTA Procedure 3A, ASTM D4169, ASTM F2096
- Sterilization evaluation to ISO 11137-1 and ISO 11137-2
- Endotoxin testing to AAMI ST72

## Clinical Testing

No clinical studies were performed.

## Conclusions

The PERFORM™ Humeral System – Stem does not raise new questions of safety or effectiveness. Differences in technological characteristics have been addressed with performance testing. The results of performance testing for the PERFORM Humeral System – Stem support substantial equivalence to the predicate AEQUALIS ASCEND™ FLEX Shoulder System (K190521, cleared on June 12, 2019).