June 14, 2019

Tornier, Inc.
Katie Molland, PhD, RAC
Senior Regulatory Affairs Specialist
10801 Nesbitt Avenue South
Bloomington, Minnesota 55340

Re: K191318
Trade/Device Name: AEQUALIS™ FLEX REVIVE™ Shoulder System
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: May 14, 2019
Received: May 15, 2019

Dear Dr. Katie Molland:

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 CAPT Raquel Peat, PhD, MPH, USPHS
Director
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)*
K191318

Device Name
AEQUALIS™ FLEX REVIVE™ Shoulder System

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 AEQUALIS™ FLEX REVIVE™ 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 AEQUALIS™ FLEX REVIVE™ 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 AEQUALIS™ FLEX REVIVE™ 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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Date Prepared: June 12, 2019

Administrative Information

Name:	Tornier, Inc.
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Contact Person:	Katie Molland, Ph.D.
Title:	Senior Regulatory Affairs Specialist
Phone:	952-683-7446
Fax:	952-426-7601

Device Information

Name of Device:	AEQUALIS™ FLEX REVIVE™ Shoulder System
Common Name (s):	Shoulder Prosthesis
Classification Name:	Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented
Regulatory Class:	II
Regulation Number:	21 CFR 888.3660, 888.3690
Product Codes:	KWS, PHX, HSD

Predicate Device Information

Predicate:	AEQUALIS™ FLEX REVIVE™ Shoulder System
510(k) Number:	K181420

Reference Device Information

Reference Device:	Biomet Comprehensive Segmental Revision System
510(k) Number:	K173411

Device Description

AEQUALIS™ FLEX REVIVE™ Shoulder System (AFR) 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. AFR 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 Ascend Flex Humeral Head and Ascend Flex reversed trays and poly inserts.

The AFR Shoulder System 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 Ascend Flex humeral heads or Ascend Flex reversed trays and inserts. In addition, the AFR Shoulder System 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

The AEQUALIS™ FLEX REVIVE™ Shoulder System is intended for replacement of the shoulder joint to reduce pain and improve shoulder mobility in comparison with preoperative status.

Indications for Use

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 AEQUALIS™ FLEX REVIVE™ 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 AEQUALIS™ FLEX REVIVE™ 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 AEQUALIS™ FLEX REVIVE™ 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.

Comparison of Technological Characteristics with the Predicate Device

New Distal Stem components will be offered in additional lengths and a partially coated format for the same intended use as the predicate device. The new stems are compatible with all existing components of the predicate AFR Shoulder System. The design differences do not raise new issues of safety or effectiveness and are supported by performance testing and process validations.

Non-clinical Performance Testing

To demonstrate substantial equivalence to the predicate device, the following non-clinical bench testing and process validations were performed as indicated by risk analysis:

- Packaging Validation Testing
- Biocompatibility Evaluation
- Press-Fit Analysis
- Simulated Use Test

The subject device passed all testing with the same acceptance criteria as the predicate device.

Clinical Testing

No clinical studies were performed.

Conclusions

The subject device is identical to the predicate device with respect to intended use, principles of operation, and conditions for use. The AEQUALIS™ FLEX REVIVE™ Shoulder System does not raise new questions of safety or effectiveness. Differences in technological characteristics that pose new potential risks as identified by risk analyses have been addressed with verification and validation testing. The results of testing for the modified AEQUALIS™ FLEX REVIVE™ Shoulder System support substantial equivalence to the current AEQUALIS™ FLEX REVIVE™ Shoulder System (K181420).