



Food and Drug Administration
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Tornier, Incorporated
Ms. Laurie Lewandowski
Regulatory Affairs Consultant
10801 Nesbitt Avenue South
Bloomington, Minnesota 55340

November 15, 2016

Re: K161742

Trade/Device Name: Aequalis PerFORM Reversed, Aequalis PerFORM+ Reversed
Glenoid

Regulation Number: 21 CFR 888.3660

Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis

Regulatory Class: Class II

Product Code: PHX, KWS

Dated: October 14, 2016

Received: October 17, 2016

Dear Ms. Lewandowski:

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. 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely,


Mark N. Melkerson -S

Mark Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K161742

Device Name
Aequalis Perform Reversed and Aequalis PerFORM+ Reversed Glenoid

Indications for Use (Describe)

The Aequalis PerFORM Reversed & Aequalis PerFORM+ Reversed Glenoid are 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
- Traumatic arthritis
- Revision of the devices if sufficient bone stock remains.

Notes:

- All components are single use.
- The glenoid sphere implant is anchored to the bone with screws and is 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.

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510(k) Summary

510(k) Number: K161742

Date Prepared: November 9, 2016

I. Administrative Information

Name: Tornier, Inc.
 Address: 10801 Nesbitt Avenue South
 Bloomington, MN 55437
 United States of America

Contact Person: Laurie Lewandowski
 Regulatory Affairs Consultant

Phone: 612-770-4038
 Fax: 952-426-7601

II. Device Information

Name of Device: Aequalis Perform Reversed and Aequalis PerFORM+ Reversed Glenoid
 Common Name: Shoulder Prosthesis
 Classification Name: 21 CFR 888.3660, shoulder joint metal/polymer or semi-constrained cemented prosthesis.
 Regulatory Class: Class II
 Primary Product Code: PHX
 Secondary Product Code: KWS

III. Predicate Device Information

Primary Predicate: Aequalis Reversed Shoulder Prosthesis, K081059
 Reference Device: Zimmer Trabecular Metal Reverse, K052906
 Reference Device: Exactech Equinox Reversed Augmented, K110708

IV. Device Description

The Aequalis[™] PerFORM Reversed and Aequalis[™] PerFORM+ Reversed Glenoid are intended to replace the glenoid part of the scapulohumeral joint as part of a reverse shoulder prosthesis. Aequalis[™] PerFORM Reversed and Aequalis[™] PerFORM+ Reversed glenoid component assembly must be used in association with a Tornier humeral component:

- Humeral implants Aequalis Reversed, Aequalis Reversed Fracture or Aequalis Adjustable Reversed Shoulder
- or Humeral implants Aequalis Ascend Flex Shoulder System in reverse configuration
- or humeral implants Aequalis Reversed FX2



The glenoid component assembly includes a modular system including a baseplate with central screw or press-fit post, peripheral anchoring screws and a glenosphere. The baseplates are available in various design configurations including: standard, lateralized, half-wedge augment and full-wedge augment. The glenospheres are available in various design configurations including: standard, lateralized and eccentric. The press-fit post may be used with the standard baseplate in lieu of the central anchoring screw. The baseplates and the press-fit posts are manufactured using additive manufacturing technology.

V. Intended Use

The Aequalis PerFORM Reversed & Aequalis PerFORM+ Reversed Glenoid are intended for replacement of the shoulder joint to reduce pain and improve shoulder mobility in comparison with preoperative status.

VI. Indications for Use

The Aequalis PerFORM Reversed & Aequalis PerFORM+ Reversed Glenoid are 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
- Traumatic arthritis
- Revision of the devices if sufficient bone stock remains.

Notes:

- All components are single use.
- The glenoid sphere implant is anchored to the bone with screws and is for non-cemented fixation.

VII. Comparison of Technological Characteristics with the Predicate Device

The Aequalis PerFORM Reversed has the same intended use and the same fundamental scientific technology as the primary predicate and reference devices. The augment baseplates are similar to those of the reference device, Exactech Equinox (K110708), both of which accommodate varying glenoid bone geometry due to wear on the articular surface. The porous structure of the baseplate is similar to that of the reference device, Zimmer Trabecular Metal Reverse, K052906 Both are designed to minimize the bone reaming needed to preserved as much of the native bone as possible. The design differences have been demonstrated to not affect safety or effectiveness or raise new issues of safety or effectiveness.

VIII. Performance Data

Non-clinical performance bench testing (mechanical testing) was performed to demonstrate substantial equivalence to the predicate device.

- Compressive Strength and Elastic Modulus Testing of Titanium Porous Metal Verification
- Titanium Porous Structure Stereological Evaluation
- Titanium Porous Structure Mechanical Verification
- PerFORM Reversed Fixation Pull-out Test
- Fatigue Test
- Range of Motion Analysis
- PerFORM Reversed Taper Pull-Off Test
- Glenoid Loosening Test (100,000 cycles)
- PerFORM+ Reversed Augment Baseplate compared to the Exactech Equinox Reverse Augmented Baseplate Analysis
- PerFORM Reversed Lateralization Comparison
- PerFORM Reversed and PerFORM+ Reversed Peripheral Screw Angulation
- Direct Metal Laser Sintering (DMLS) Process Validation
- Operational Qualification – Mechanical Validation & Microstructure Validation
- Performance Qualification – Mechanical Validation & Microstructure Validation
 - Powder Bed Position Validation
 - Powder Recycling Validation
 - Powder Removal Validation
- DMLS Device Powder Removal Cleaning
- DMLS Titanium Material Validation
- Endotoxin (<20 EU / device)

IX. Clinical Study

Clinical studies were not required to demonstrate substantial equivalence between the subject device and the predicate device.

X. Conclusions

The Aequalis PerFORM Reversed and Aequalis PerFORM+ Reversed Glenoid described in this section has the same intended use and the same fundamental scientific technology as the cleared Aequalis Shoulder Prosthesis, the porous structure is similar to the Trabecular Metal Reverse, and lateralization and augmentation are similar to Equinox Reverse Augmented Shoulder Prosthesis. Based on the testing presented for the design differences between the subject and predicate device, Tornier concludes that subject device is substantially equivalent to the predicate device.