January 30, 2019

Tornier, Inc.
Moyees Kamara
Regulatory Affairs Specialist
10801 Nesbitt Avenue South
Bloomington, Minnesota 55347

Re: K183696
Trade/Device Name: Aequalis PerFORM Reversed Glenoid, 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: December 28, 2018
Received: December 31, 2018

Dear Moyees Kamara:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi -S

Digitally signed by Vesa Vuniqi -S
Date: 2019.01.30 17:08:35 -05'00'

For: Mark N. 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

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*

K183696

Device Name

Aequalis™ PerFORM™ Reversed Glenoid 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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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."*

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Date Prepared: December 28, 2018

**Administrative Information**


| | |
|---|---|
| Name: | Tornier, Inc. |
| Address: | 10801 Nesbitt Avenue South<br>Bloomington, MN 55437<br>United States of America |
| Contact Person: | Moyees Kamara, Jr. |
| Title: | Regulatory Affairs Specialist |
| Phone: | 952.426.7637 |
| Fax: | 952.426.7601 |
| Email: | moyees.kamarajr@wright.com |


**Device Information**

| | |
|---|---|
| Name of Device: | Aequalis™ PerFORM™ Reversed Glenoid and Aequalis™ PerFORM™+ Reversed Glenoid |
| Common Name (s): | Shoulder Prosthesis |
| Regulatory Class: | Class II |
| Regulation: | 21 CFR § 888.3660, Shoulder joint metal/polymer semi-constrained cemented prosthesis. |
| Product Codes: | PHX, KWS |

**Predicate Device Information**

| | |
|---|---|
| Predicate: | Aequalis™ PerFORM™ Reversed Glenoid and Aequalis™ PerFORM™+ Reversed Glenoid |
| 510(k) Number: | K161742 |

**Device Description**

The Aequalis™ PerFORM™ Reversed Glenoid and Aequalis™ PerFORM™+ Reversed Glenoid shoulder system is a modular system consisting of a Glenoid Component Assembly and a Humeral Component Assembly for total shoulder arthroplasty. The associated shoulder surgical instruments are intended to facilitate proper implantation of this shoulder system. The Aequalis™ PerFORM™ Reversed Glenoid and Aequalis™ PerFORM™+ Reversed Glenoid shoulder system is designed and indicated for replacement of the shoulder joint to reduce pain and improve shoulder mobility in comparison with preoperative status.

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**Intended Use**

The Aequalis™ PerFORM™ Reversed Glenoid and Aequalis™ PerFORM™+ Reversed Glenoid are intended for replacement of the shoulder joint to reduce pain and improve shoulder mobility in comparison with preoperative status. The subject device and predicate device have the same intended use.

**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.

**Comparison of Technological Characteristics with the Predicate Device**

The proposed changes to the predicate device include the addition of a short (7 mm) Press-fit Post; use of both the short and long (15 mm) Press-fit Post lengths with the Half-Wedge Augment Baseplate and Full-Wedge Augment Baseplate; and the inclusion of three additional drills. The subject device has the same intended use and the fundamental scientific technology as the predicate device. 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**

Non-clinical bench testing and process validations were performed to demonstrate substantial equivalence of the subject device to the predicate device.

**Performance Data**

Risk analyses and device testing were performed and demonstrated that:

1) The addition of a short Press-fit Post to the Aequalis™ PerFORM™ Reversed Glenoid and Aequalis™ PerFORM™+ Reversed Glenoid shoulder system meets the device testing acceptance criteria described in the predicate submission (K161742), and is substantially equivalent to predicate long Press-fit Post.
2) Both the short and the long Press-fit Posts can be configured with the Half-Wedge Augment Baseplate and Full-Wedge Augment Baseplate. These configurations meet the appropriate acceptance criteria.

**Clinical Testing**

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

**Conclusions**

The Aequalis™ PerFORM™ Reversed Glenoid and Aequalis™ PerFORM™+ Reversed Glenoid shoulder system 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 subject device support substantial equivalence to the current predicate device.