



Food and Drug Administration  
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June 10, 2016

Tornier, Incorporated  
Ms. Loucinda Bjorklund  
Manager, Regulatory Affairs  
10801 Nesbitt Avenue South  
Bloomington, Minnesota 55437

Re: K160975

Trade/Device Name: Aequalis PerFORM+ 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  
Dated: May 10, 2016  
Received: May 11, 2016

Dear Ms. Bjorklund:

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 yours,

**Mark N. Melkerson -S**

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

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

## Indications for Use

510(k) Number (if known)

K160975

Device Name

Aequalis PerFORM+ Shoulder System

Indications for Use (Describe)

Prosthetic replacement with this device (Aequalis PerFORM+ glenoid component and humeral component) may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies: arthrosis, rheumatoid arthrosis, post traumatic arthrosis
- Primary and secondary necrosis of the humeral head
- Displaced 4-part upper humeral fracture
- Humeral head fracture
- Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
- Revision surgery when other treatments or devices have failed

The Aequalis PerFORM+ glenoids are intended for cemented use only.

The Aequalis monobloc stem is for cemented use

The Aequalis Press-Fit is for uncemented use

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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Special Premarket Notification 510(k)  
Aequalis PerFORM+ Shoulder System  
Tornier, Inc.

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## **510(k) Summary**

### **K160975**

#### **I. Submitter**

Tornier, Inc.  
10801 Nesbitt Avenue South  
Bloomington, MN 55437

Date Prepared: June 8, 2016  
Contact Person: Loucinda Bjorklund  
Manager, Regulatory Affairs  
Phone: 952-683-7491  
Fax: 952-426-7601

#### **II. Device**

Name of Device: Aequalis PerFORM+ Shoulder System  
Common or Usual Name: Shoulder Prosthesis, humeral head  
Classification Name: 21 CFR 888.3660, shoulder joint metal/polymer semi-constrained cemented prosthesis  
Regulatory Class: Class II  
Product Code: KWS

#### **III. Predicate Device**

Aequalis PerFORM+ Shoulder System, K150583

#### **IV. Device Description**

The Aequalis PerFORM+ Shoulder System is a modular system consisting of a metaphyseal humeral stem component, anatomic humeral heads and glenoid for a total shoulder arthroplasty. Surgical instruments are designed to facilitate proper implantation of the system.

#### **V. Intended Use**

The Tornier shoulder prostheses are intended for replacement of the shoulder joint to reduce pain and improve shoulder mobility in comparison with preoperative status.

## VI. Indications For Use

Prosthetic replacement with this device (Aequalis PerFORM+ glenoid component and humeral component) may be indicated to relieve severe pain or significant disability caused by:

- Degenerative pathologies: arthrosis, rheumatoid arthritis, post-traumatic arthrosis.
- Primary or secondary necrosis of the humeral head.
- Displaced 4-part upper humeral fracture
- Humeral head fracture
- Other pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable.
- Revision surgery when other treatments or devices have failed.

The Aequalis PerFORM+ glenoids are intended for cemented use only.

The Aequalis monbloc stem is for cemented use

The Aequalis press-fit is for uncemented use

## VII. Comparison of Technological Characteristics with the Predicate Device

The Aequalis PerFORM+ Shoulder System has the same intended use and fundamental scientific technology as the predicate device. The design differences do not affect safety or effectiveness or raise new issues of safety or effectiveness.

## VIII. Non-Clinical Performance Data

The following performance data were provided in support of the substantial equivalence determination.

### Performance Data

Validation and / or Verification Method	Acceptance Value / Criteria	Results
Loosening Test	No Loosening detected at completion of test.	Acceptable
Shear testing	Comparable to the predicate device design.	Acceptable
Tensile (pull out) testing	Comparable to the predicate device design.	Acceptable
Endotoxin	≤ 20 EU / device	Acceptable

## 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+ Shoulder System described in this section has the same intended use and the same fundamental scientific technology as the cleared Aequalis Shoulder System. Based on the testing presented for the design differences between the subject and predicate devices, Tornier concludes that subject device is substantially equivalent to the predicate device.