



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Tornier, Incorporated
Kris Miller
Senior Regulatory Specialist
10801 Nesbitt Avenue South
Bloomington, Minnesota 55437

May 8, 2015

Re: K150583

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: March 25, 2015
Received: March 26, 2015

Dear Kris Miller:

This letter corrects our substantially equivalent letter of April 23, 2015.

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 Part 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

INDICATIONS FOR USE

510(k) Number (if known): K150583

Device Name: Aequalis PerFORM+ Shoulder System

Indications for Use:

Prosthetic replacement with this device 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 monobloc stem is cemented use.

The Aequalis press-fit is for uncemented use.

Glenoid component is for cemented use.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Aequalis PerFORM+ Shoulder System
Tornier, Inc.

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510(k) Summary

I. Submitter

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

Date Prepared: March 4, 2014
Contact Person: Kris Miller
Senior Regulatory Affairs Specialist
Phone: 952-426-7652
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 Shoulder System, K111902
Depuy Steptech, K092122
Exactech Equinox, K121220

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.

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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 monobloc stem is cemented use.

The Aequalis press-fit is for uncemented use.

Glenoid component is for cemented 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 have been demonstrated to not affect safety or effectiveness or raise new issues of safety or effectiveness.

VIII. Performance Data

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

Table 1 Performance Data

Validation and / or Verification Method	Acceptance Value / Criteria	Results
Dimensional comparison	The profile and anchorage of the Aequalis PerFORM+ to be the same as to the predicate device design.	Acceptable
Dimensional comparison	The geometric shape of the articular surface must be compatible with existing humeral heads.	Acceptable
Dimensional comparison	Posterior build up must be equivalent to the currently marketed devices.	Acceptable
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
Simulated use of instrumentation	Successful preparation of cadaveric specimens.	Acceptable

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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.