DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

November 2, 2016

Tornier, Incorporated
Mr. Brahim Hadri
Senior Regulatory Affairs Specialist
7701 France Avenue South, Suite 600
Edina, Minnesota 55435

Re: K120739
Trade/Device Name: Aequalis Adjustable Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, KWT, HSD
Dated: June 27, 2012
Received: June 28, 2012

Dear Mr. Hadri:

This letter corrects our substantially equivalent letter of July 5, 2012.

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,

Lori A. Wiggins -S

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

Enclosure

K120739

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Indications for Use

510(k) Number (if known): K120739

Device Name: **Aequalis Adjustable Reverse Shoulder System**

Indications for Use

The Aequalis Adjustable Reverse Shoulder System is indicated for patients with a functional deltoid muscle and a massive and non-repairable rotator cuff tear 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 the devices if sufficient bone stock remains

Notes:

- All components are single use
- **The humeral stems:**
  - The **uncoated** humeral stems are for **cemented or cementless** use;
  - The **hydroxylapatite coated** stems are for **cementless use only**
- **The glenoid implant** is anchored to the bone with 4 screws and is for non-cemented fixation.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120739

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SECTION 5

510(k) SUMMARY

JUL 5 2012

Summary of Safety and Effectiveness information

Tornier Inc. Aequalis Adjustable Reverse Shoulder System

Regulatory authority: Safe Medical Devices Act of 1990, 21 CRF 807.92

1) **Device name**

Trade name: **Aequalis Adjustable Reverse Shoulder System**
Common name: Shoulder Prosthesis
Classification Number/ Classification name/Product code:

- Shoulder joint metal/polymer non-constrained cemented prosthesis are class II devices under 21 CFR 888.3650 (product code KWT) and are classified by the Orthopedic Devices Panel
- Shoulder joint metal/polymer semi-constrained cemented prosthesis are class II devices under 21 CFR 888.3660 (product code KWS) and are classified by the Orthopedic Devices Panel
- Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis are class II devices under CFR 888.3690 (product code HSD) and are classified by the Orthopedic Devices Panel

2) **Submitter**

Tornier Inc.
7701 France Avenue South; Suite 600
Edina, MN 55435
Registration Number: 9100540

3) **Company contact**

Brahim Hadri
Sr. Regulatory affairs Specialist
Telephone: 781-249-8030
Fax: 952-426-7601
Email: bhadri@tornier.com

4) **Classification**

Device class:	Class II
Classification panel:	Orthopedic
Product code:	**KWT; KWS; HSD**

5) **Legally Marketed Device to which Equivalence is Claimed:**

- Tornier Aequalis Ascend Modular Anatomic Shoulder Prosthesis: K102924
- Tornier Aequalis® Ascend™ Modular Reverse Shoulder System K110599
- Tornier Aequalis Reversed Shoulder Prosthesis: K081059
- Tornier Aequalis Reversed Shoulder Prosthesis (HAP Coated): K100142
- Tornier Aequalis Reversed Fracture Shoulder Prosthesis: K082120

6) **Device description**

The Aequalis Adjustable Reverse Shoulder system is a modular Reverse version of the Aequalis Shoulder System (K100142, K081059).

The Aequalis Adjustable Reverse Shoulder system is supplied in separate, sterile packages which will be assembled in the operating room. The components provided will be:

- Metaphysis
- Stem Spacers
- Stems
- Assembly Screw
- Securitization System: Securitization Bracket and Screw

Primary Reverse Shoulder:

The Aequalis Adjustable Reverse Shoulder is a modular version of the Aequalis Reverse shoulder system. The Aequalis Adjustable Reverse Shoulder system has the same indications as Tornier Aequalis® Ascend™ Modular Reverse Shoulder System K110599.

The Aequalis Adjustable Reverse Shoulder system contains a set of anatomically sized metaphyseal, spacers, and tapered stems that will be used in conjunction with the existing Aequalis Reverse glenosphere and polyethylene inserts for reversed total shoulder arthroplasty.

The device will have a series of modular stems and spacers to accommodate a varied patient population. The system will include 10 stems: Five 90mm length (9, 11, 13, 15,. 17mm diameter) and five 110mm length stems with 3 options:

- Uncoated,
- Hydroxylapatite (HAP) coated,
- HAP over titanium plasma spray (HAP/Ti PS) coated.

The Aequalis Adjustable Reverse Shoulder assembly must be used in association with the Aequalis Reversed or Aequalis Reversed II glenoid implants, screws and fracture inserts (K030941, K061439, K081059, K050316, and K082120).

7) **Materials**

The material used in the composition of the Aequalis Adjustable Reverse Shoulder implants is as follows:

- Humeral stems are manufactured from titanium alloy (Ti6Al4V) according to ISO 5832-3 and are available in 3 options:
  - 1) **Uncoated,**
  - 2) **Hydroxylapatite (HAP) coated** according to ASTM F-1185
  - 3) **HAP coated over titanium plasma spray (HAP/Ti PS)** according to ASTM F-1185 and ASTM F-1580
- Metaphysis components are manufactured from titanium alloy (Ti6Al4V) according to ISO 5832-3
- Spacers are manufactured from titanium alloy (Ti6Al4V) according to ISO 5832-3
- Assembly screws are manufactured from chromium cobalt alloy (CoCr) according to ISO 5832-7
- The Secularization System Screw and Bracket are manufactured from titanium alloy (Ti6Al4V) according to ISO 5832-3 and chromium cobalt alloy (CoCr) according to ISO 5832-7 respectively

8) Indications for Use

The Aequalis Adjustable Reverse Shoulder System is indicated for patients with a functional deltoid muscle and a massive and non-repairable rotator cuff tear as a replacement of Shoulder joints disabled by:

- Rheumatoid arthritis with pain
- Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascular necrosis)
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Notes:

- All components are single use
- The humeral stems:
  - The uncoated humeral stems are for cemented or cementless use;
  - The hydroxylapatite coated stems are for cementless use only
- The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

9) Summary of technologies

In addition to the technological characteristics (material, design, sizing, indications) of the Tornier Aequalis Adjustable Reverse Shoulder System being similar or identical to the cited predicate devices; the Aequalis Adjustable Reverse Shoulder System was subjected to non-clinical testing such as simulated use testing; fatigue testing; Galvanic Fretting Corrosion testing. Tornier concludes that its Aequalis Adjustable Reverse Shoulder System described in this submission is substantially equivalent and as safe and effective as the cited predicate device.