DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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November 2, 2016

Tornier, Incorporated
Ms. Kristine Tucker
Regulatory Affairs Director
10801 Nesbitt Avenue South
Bloomington, Minnesota 55437

Re: K141029
Trade/Device Name: Aequalis Adjustable Reversed 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
Dated: May 22, 2014
Received: May 27, 2014

Dear Ms. Tucker:

This letter corrects our substantially equivalent letter of June 18, 2014.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K141029

Device Name
Aequalis Adjustable Reversed Shoulder System

Indications for Use *(Describe)*
The Aequalis Adjustable Reversed 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 titanium plasma spray coated stems are for cemented or cementless use;
- The hydroxylapatite coated stems are for cementless use only
- The hydroxylapatite over titanium plasma spray coated stems are for cementless use only

The glenoid implant is anchored to the bone with 4 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

TORNIER

JUN 18 2014

4 510(k) Summary

510(K) Owner's Name:	Tornier Inc.
Address:	10801 Nesbitt Avenue South Bloomington, Minnesota 55437
Phone and Fax Numbers:	Phone: 952.426.7600 Cell Phone: 952.491.1451 Fax: 952.426.7601
Name of Contact Person:	Kristine Tucker
Date Prepared:	June 16, 2014
Trade or Proprietary Name:	Tornier Aequalis Adjustable Reverse Shoulder System
Common or Usual Name:	Shoulder joint metal/polymer prosthesis
Classification Name:	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
Legally Marketed Device to Which Your Firm Is Claiming Equivalence:	Tornier Aequalis Adjustable Reverse Shoulder System, K120739, cleared on July 5, 2012.
Description of The Device:	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). The purpose of this 510(k) is to add an additional stem configuration that does not have HAP Coating and that has plasma titanium spray coating on a portion of the stem (20mm proximal portion of stem), and has a fluted surface on a portion of the stem instead of the full length of the stem (i.e., the HAP coating and fluted surface on 20mm proximal portion of stem. In addition, an alternate plasma titanium spray coating supplier has been validated to perform this manufacturing operation.
Intended Use of the Device:	The Aequalis Adjustable Reversed 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 titanium plasma spray coated stems are for cemented or cementless use; • The hydroxylapatite coated stems are for cementless use only • The hydroxylapatite over titanium plasma spray coated stems are for cementless use only The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.
Technological Characteristics Compared To Predicate Device:	The technological characteristics (material, design, sizing, indications, sterilization, and failure strength) of the Tornier Aequalis Adjustable Reverse Shoulder System are substantially equivalent to the predicate device.
Summary of the Nonclinical Tests Submitted:	Non-clinical laboratory assessment/testing was performed to evaluate the device performance per design requirements and risk analysis, including demonstration of design equivalence, fatigue testing, shear fatigue strength, static shear strength per ASTM F1044, static tensile strength per ATM F1147, abrasion resistance per ASTM F1978, thickness per ASTM F1854, mean void intercept length per ASTM F1854, and mean volume percent of void per ASTM F1854. All testing results met pre-established acceptance criteria.
Conclusions Drawn From the Nonclinical and Clinical Tests:	Based on risk analysis and acceptable results from testing, the Tornier Aequalis Adjustable Reverse Shoulder System was found to be substantially equivalent to the predicate device.