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 SAS
Mr. Aymen Azaiez
Regulatory Affairs Specialist
161 rue Lavoisier
38334 Montbonnot Cedex
FRANCE

Re: K140082
Trade/Device Name: Aequalis™ Ascend™ Flex 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 17, 2014
Received: June 19, 2014

Dear Mr. Azaiez:

This letter corrects our substantially equivalent letter of July 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 on last page.*

510(k) Number *(if known)*
Ki40082

Device Name
Aequalis™ AscendTM Flex Shoulder System

Indications for Use *(Describe)*
SYSTEM INTENDED USE:
The Aequalis Ascend Flex Shoulder System is intended for use as:
• A replacement of shoulder joints in primary anatomic or in primary reverse.
• A replacement of other shoulder joints devices in case of revisions if sufficient bone stock remains.
• The Aequalis Ascend Flex Shoulder System also allows for conversions from anatomic to reverse shoulder prosthesis in case of revision.
IN ANATOMIC: The stem and head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement.
The Aequalis Ascend Flex Shoulder System is to be used only in patients with an intact or reconstructable rotator cuff, where it is intended to provide increased mobility and stability and to relieve pain.
The Aequalis Ascend Flex Shoulder System is indicated for use as a replacement of shoulder joints disabled by:
• Rheumatoid arthritis with pain
• Non-inflammatory degenerative joint disease (i.e. osteoarthritis and avascu Jar necrosis)
• Correction of functional deformity
• Fractures of the humeral head
• Traumatic arthritis
• Revision of other devices if sufficient bone stock remains
IN REVERSE: The Aequalis Ascend Flex Shoulder System is 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.
The reversed adapter is indicated for use as components of the Aequalis Ascend Flex Shoulder System total shoulder replacement and for transformation of the Aequalis Ascend Flex Shoulder System into a reverse shoulder prosthesis without the removal of the humeral stem during revision surgery for patients with a functional deltoid muscle. The components are permitted to be used in the transformation from anatomic to reverse if the humeral stem is well fixed, the patient has a functional deltoid muscle; the arthropathy is associated with a massive and non-repairable rotator cuff-tear.
Notes: All components are single use; The coated humeral stem is intended for cemented or cementless use; The non-coated humeral stem is intended for cemented use only; All poly glenoid components are intended for cemented use only; The glenoid sphere implant is anchored to the bone with screws and is for non-cemented fixation.; Titanium humeral heads are intended for patients with suspected cobalt alloy material sensitivity. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A titanium humeral head is not recommended for patients who lack a suspected material sensitivity to cobalt alloy.

Type of Use *(Select one or both, as applicable)*

Prescription Use (Part 21 CFR 801 Subpart D) O 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)*

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510(k) SUMMARY

JUL 1 8 2014

Summary of Safety and Effectiveness information

510(k) Premarket Notification – Aequalis™ Ascend™ Flex Shoulder System

Date prepared: July 17, 2014

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

1) Device name

Trade name: Aequalis™ Ascend™ Flex Shoulder System
Common name: Shoulder Prosthesis
Classification name:

- 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 SAS
161 rue Lavoisier
38330 Montbonnot Saint Martin- France
Registration Number: 3000931034

3) Company contact

Tornier
Mr Aymen AZAIEZ
Regulatory Affairs Specialist
Tornier
161 rue Lavoisier
38330 Montbonnot Saint Martin- France

Tel: 00 33 4 76 61 35 00 Fax: 00 33 4 76 61 35 59
E-mail: aymen.azaiez@tornier.com

4) Classification

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

5) Equivalent / Predicate device

Tornier SAS: Aequalis™ Ascend™ Flex Shoulder System (K122698)

Tornier SAS: Aequalis® Shoulder System (K952928)

6) Device description

The Aequalis Ascend Flex Shoulder System consists of:

- **In a Anatomic configuration:** A titanium humeral stem offered in Titanium Plasma Spray (Ti PS) coated and un-coated stem versions, a compatible humeral head (CoCr) with a compatible UHMWPE Aequalis glenoid; or UHMWPE Affiniti Anatomic glenoid.
  The Aequalis Ascend Flex Shoulder System stem and head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with a glenoid, as a total shoulder joint replacement.
- **In a Reversed configuration:** a titanium humeral stem offered in Titanium Plasma Spray (Ti PS) coated and un-coated stem versions, a reversed adapter with compatible Aequalis Reversed glenoid implants.
  The reversed adapter is comprised of two components: a titanium tray and a UHMWPE reversed insert.
  The Aequalis Reversed glenoid implants is comprised of four components: Baseplate: made from Titanium; Glenoid sphere: made from of CoCr; Screw (baseplate/to glenoid sphere): made from CoCr and Fixation screws: made from Titanium.

The Aequalis Ascend Flex Shoulder System is 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.
This submission corresponds to the addition of Titanium Humeral Heads in anatomic to the Aequalis™ Ascend™ Flex Shoulder System.

7) Materials

The Aequalis™ Ascend™ Flex Shoulder System titanium humeral head is manufactured from Ti6Al4V according to ISO 5832-3 standard.

8) Indications for use

SYSTEM INTENDED USE:
The Aequalis Ascend Flex Shoulder System is intended for use as:

- A replacement of shoulder joints in primary anatomic or in primary reverse.
- A replacement of other shoulder joints devices in case of revisions if sufficient bone stock remains.
- The Aequalis Ascend Flex Shoulder System also allows for conversions from anatomic to reverse shoulder prosthesis in case of revision.

IN ANATOMIC: The stem and head may be used by themselves, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement.
The Aequalis Ascend Flex Shoulder System is to be used only in patients with an intact or reconstructable rotator cuff, where it is intended to provide increased mobility and stability and to relieve pain.
The Aequalis Ascend Flex Shoulder System is indicated for use 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 other devices if sufficient bone stock remains

IN REVERSE: The Aequalis Ascend Flex Shoulder System is 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

The reversed adapter is indicated for use as components of the Aequalis Ascend Flex Shoulder System total shoulder replacement and for transformation of the Aequalis Ascend Flex Shoulder System into a reverse shoulder prosthesis without the removal of the humeral stem during revision surgery for patients with a functional deltoid muscle. The components are permitted to be used in the transformation from anatomic to reverse if the humeral stem is well fixed, the patient has a functional deltoid muscle: the arthropathy is associated with a massive and non-repairable rotator cuff-tear.

Notes:

- All components are single use.
- The coated humeral stem is intended for cemented or cementless use.
- The non-coated humeral stem is intended for cemented use only.
- All poly glenoid components are intended for cemented use only.
- The glenoid sphere implant is anchored to the bone with screws and is for non-cemented fixation.
- Titanium humeral heads are intended for patients with suspected cobalt alloy material sensitivity. The wear properties of Titanium and Titanium alloys are inferior to that of cobalt alloy. A titanium humeral head is not recommended for patients who lack a suspected material sensitivity to cobalt alloy.

9) Summary of technological characteristics

Main features or system characteristics		*Aequalis Ascend Flex Shoulder System* Humeral Heads (titanium)		*Aequalis Ascend Flex Shoulder System* Humeral Heads (Cobalt Chrome)		*Aequalis Shoulder System* Aequalis Humeral Heads	*SE?*
		Aequalis Humeral Heads	*Soft Tissue Balancing (STB) Humeral Heads*	*Aequalis Humeral Heads*	*Soft Tissue Balancing (STB) Humeral Heads*		
Material		Ti6Al4V		CoCr		Ti6Al4V [1]	Yes
Standard		ISO 5832-3		ISO 5832-7 or ISO 5832-12		ISO 5832-3	Yes
Dimensions	**Diameter**	37mm to 54mm	39mm to 55.4mm	37mm to 54mm	39mm to 55.4mm	39mm to 50mm	Yes
	Height	13.5mm to 27mm	13mm to 24mm	13.5mm to 27mm	13mm to 24mm	14mm to 16mm	Yes
	Eccentricity	1.5mm; 3.5mm and 4mm		1.5mm; 3.5mm and 4mm		2mm; 2.2mm; 2.3mm; 3mm;3.9mm et 4.7mm	Yes
Taper gender geometry		Male		Male		Female	Yes
Manufacturer		Tornier		Tornier		Tornier	Yes
Terminal sterilization		Yes		Yes		Yes	Yes
K-number		Pending		K122698		K952928	Yes

The indications for use, the technical characteristics (materials, manufacturing principle and method of fixation), the packaging and the sterilization process of they are similar or identical to the predicate devices.

10) Non-clinical testing

Three non-clinical testing were realized on the titanium humeral heads:

- Wear test:

The aim of the test is to demonstrate that the Titanium humeral head remain intact during its lifetime. Therefore, we have tested the wear of the frictional couple Ti / UHMWPE and compared the results with those of the frictional couple CoCr/UHMWPE.

The results of this test are equivalent between the two frictional couples CoCr / UHMWPE (already used in the predicate device "Aequalis Ascend Flex Shoulder System") and TI / UHMWPE in terms of: weight loss, wear rate and shape and size of the particles generated.

- Anatomical Fatigue Test:

The aim of the test is to show that the Aequalis™ Ascend Flex Shoulder System in anatomical configuration remains intact during its lifetime. The assembly humeral head/ stem must resist in normal conditions of use.

After applying a load for 5M cycles, we have observed neither fracture nor damage. Thus, the Aequalis™ Ascend Flex Shoulder System in anatomical configuration is validated with the titanium humeral head as is the case with the CoCr humeral head (predicate device).

- Reversed fatigue test:

The aim of the test is to show that the Aequalis™ Ascend Flex Shoulder System in reversed configuration remains intact during its lifetime after revision from an anatomical configuration to a reversed configuration after a first lifetime in an anatomical configuration. The assembly humeral head/ stem must resist in normal conditions of use.

After applying a load for 5M cycles, we have observed neither fracture nor damage. Thus, the Aequalis™ Ascend Flex Shoulder in reversed configuration after revision from an anatomical configuration to a reversed configuration after a first lifetime in an anatomical configuration with the titanium humeral head is validated as is the case with the CoCr humeral head (predicate device).

11) Substantial equivalence conclusion

Substantial equivalence of the ***Aequalis Ascend Flex Shoulder System*** *titanium humeral heads* to the already cleared components of the predicates can be demonstrated on the following grounds, according to the FDA's Guidelines for Substantial Equivalence Decision Making Process:

- The ***Aequalis Ascend Flex Shoulder System*** *titanium humeral heads* are compared to the predicate devices.

- The ***Aequalis Ascend Flex Shoulder System*** *Titanium humeral heads* have the same intended use and the same indications for use as the cleared ***Aequalis Ascend Flex Shoulder System*** *Cobalt Chrome humeral heads.*

- The ***Aequalis Ascend Flex Shoulder System*** *titanium humeral heads* have equivalent intended use and indications for use as *Aequalis Shoulder System Aequalis Humeral Head in titanium.*

- Major technological characteristics are equivalent between the ***Aequalis Ascend Flex Shoulder System titanium humeral heads*** and the predicate devices:
  - Equivalence of general features
  - Equivalent technological features: materials
  - Equivalent biomechanical features: mechanical characteristics, congruence of articular surfaces.
  - Equivalent means of fixation (Taper gender geometry)
  - Equivalent prosthetic dimensions

Therefore, in light of the above information, the company believes that the ***Aequalis Ascend Flex Shoulder System with titanium humeral heads*** may be cleared via the 510(k) notification process for use as shoulder prosthesis.