



Food and Drug Administration
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Tornier SAS
Séverine Bonneton
Regulatory Affairs Manager, New Products
161 Rue Lavoisier
38334 Montbonnot Saint Martin
France

September 24, 2015

Re: K151293

Trade/Device Name: Aequalis™ Ascend™ Flex Shoulder System, Aequalis Reversed
Prosthesis

Regulation Number: 21 CFR 888.3660

Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis

Regulatory Class: Class II

Product Code: KWS, PHX, KWT, HSD

Dated: August 25, 2015

Received: August 27, 2015

Dear Séverine Bonneton:

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" (21 CFR 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

Indications for Use*See PRA Statement below.*

510(k) Number (if known)

K151293

Device Name

Aequalis™ Ascend™ Flex Shoulder System, Aequalis Reversed Shoulder Prosthesis

Indications for Use (Describe)

Device Name : Aequalis™ Ascend™ Flex Shoulder System

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 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 for cemented use only.
- the 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.

Device Name: Aequalis Reversed Shoulder Prosthesis

Indications For Use:

Cemented Aequalis Reversed prosthesis:

It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated with the massive and non-repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non-repairable rotator cuff-tear. Only the humeral components are for cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non-reversed hemi-prosthesis.

When, in case of revision of a Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Aequalis Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis in to a non-reversed hemi-prosthesis in order to avoid the revision of the humeral components.

Uncemented Aequalis Reversed prosthesis:

It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive and non-repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non-repairable rotator cuff-tear. The humeral components are for uncemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis in to a non-reversed hemi-prosthesis.

When, in case of revision of an Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Aequalis Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis in to a non-reversed hemi-prosthesis in order to avoid the revision of the humeral components.

Note:

- Titanium glenoid spheres 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 glenoid sphere 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)

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

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Summary of Safety and Effectiveness information

Special 510(k) Premarket – Aequalis™ Ascend™ Flex Shoulder System, Aequalis Reversed Shoulder Prosthesis

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

Date prepared: September 17, 2015

1) Device name

Trade name: *Aequalis™ Ascend™ Flex Shoulder System*

Common name: Shoulder Prosthesis

Classification name:

- Shoulder joint metal/polymer semi-constrained cemented prosthesis are class II devices under 21 CFR 888.3660 (product code KWS ; PHX) and are classified by the Orthopedic Devices Panel
- 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 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

Trade name: *Aequalis Reversed Shoulder Prosthesis*

Common name: Shoulder Prosthesis

Classification name: Shoulder joint metal/polymer semi-constrained cemented prosthesis under 21CFR 888.3660 (product code PHX, KWS) and are classified by the Orthopedic Devices Panel

2) Submitter :

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SIRET : 070 501 275 000 21
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CODE APE : 3250 A

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4) Classification

Aequalis™ Ascend™ Flex Shoulder System :

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

Aequalis Reversed Shoulder Prosthesis :

Device class: Class II
Classification panel: Orthopedic
Product code: PHX, KWS

5) Equivalent / Predicate device :

Aequalis™ Ascend™ Flex Shoulder System :

Aequalis Ascend Flex Shoulder System, Tornier K122698, K140082

Aequalis Reversed Shoulder Prosthesis, Tornier, K030941, K050316, K061439, K081059, K100142, K132285, K140478

Surgical Reverse Shoulder Prosthesis (RSP), DJO, K041066, K051075, K092873, K112069, K140904

Aequalis Reversed Shoulder Prosthesis :

Aequalis Reversed Shoulder Prosthesis, TORNIER, K030941, K050316, K061439, K081059, K100142, K132285, K140478

Surgical Reverse Shoulder Prosthesis (RSP), DJO, K041066, K051075, K092873, K112069, K140904

6) Device description :

Aequalis™ Ascend™ Flex Shoulder System & Aequalis Reversed :

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.

The *Aequalis Reversed Shoulder Prosthesis* is intended to be used to relieve pain and significant disability following massive and non repairable cuff-tear associated to arthropathy and following massive cuff-tear arthropathy. It is a semi-constrained system composed of a humeral and a glenoid parts.

The Aequalis Ascend Flex Shoulder System consists of:

- **In an Anatomic configuration:** A titanium humeral stem offered in Titanium Plasma Spray (Ti PS) coated and un-coated stem versions, a compatible humeral head (CoCr or titanium) 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 compatible with **Aequalis Reversed glenoid implants** (consisting of a **sphere**, a baseplate and screws). The reversed adapter consists of two



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components: a titanium tray and a UHMWPE **reversed insert** which includes a titanium locking ring.

This submission corresponds to the addition of new reversed inserts *Aequalis Ascend Flex* and glenoid spheres *Aequalis Reversed II* in diameter 33 mm and 39 mm compatible with each other. The indications for use, the materials, the manufacturing principle, the method of fixation, the packaging and the sterilization process of the pending reversed insert and glenoid spheres are identical or equivalent to the predicate devices.

7) Materials :

Aequalis™ Ascend™ Flex Shoulder System reversed inserts :

The new reversed inserts are manufactured from Ultra High Molecular Weight Polyethylene (UHMWPE). The reversed insert includes a locking ring which is manufactured from titanium (Ti6Al4V).

Aequalis Reversed Shoulder Prosthesis glenoid spheres:

The new glenoid spheres are manufactured from titanium alloy (Ti6Al4V) and chrome cobalt.

8) Indications :

Aequalis™ Ascend™ Flex Shoulder System :

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



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- 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.

Aequalis Reversed Shoulder Prosthesis :

Cemented Aequalis Reversed prosthesis :

It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated with the massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. Only the humeral components are for cemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid bone stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis into a non reversed hemi-prosthesis.



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When, in case of revision of a Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of Aequalis Reversed range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the Aequalis Reversed prosthesis in to a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

Uncemented Aequalis Reversed prosthesis:

It is indicated for patients with a functional deltoid muscle as a total shoulder replacement for the relief of pain and significant disability following arthropathy associated to massive and non repairable rotator cuff-tear. This device is also indicated for the prosthetic revisions with massive and non repairable rotator cuff-tear. The humeral components are for uncemented use. The glenoid implant is anchored to the bone with 4 screws and is for non-cemented fixation.

When during the primary surgery the glenoid stock appears to be insufficient to bear the reversed glenoid components or when glenoid bone fracture occurs during the surgical procedures, the hemi-prosthesis adaptor and the union screw can be adapted to the humeral components in order to transform the Aequalis Reversed prosthesis in to a non reversed hemi-prosthesis.

When, in case of revision of an Aequalis Reversed prosthesis, the glenoid bone stock appears to be insufficient to again implant a base plate and a sphere of *Aequalis Reversed* range, the use of the hemi-prosthesis adaptor and the union screw allows for the transformation of the *Aequalis Reversed* prosthesis in to a non reversed hemi-prosthesis in order to avoid the revision of the humeral components.

Note:

- Titanium glenoid spheres 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 glenoid sphere is not recommended for patients who lack a suspected material sensitivity to cobalt alloy.

9) Summary of technological characteristics

Aequalis™ Ascend™ Flex Shoulder System reversed inserts :

Main features or system characteristics	Aequalis Ascend Flex Shoulder System reversed configuration (pending reversed inserts)	Aequalis Ascend Flex Shoulder System reversed configuration (cleared reversed inserts)	Aequalis Reversed Shoulder Prosthesis (reversed inserts)	Surgical Reverse Shoulder Prosthesis (RSP) (reversed inserts)
Material	Polyethylene +titanium (locking ring)	Polyethylene +titanium (locking ring)	Polyethylene	Polyethylene
Reversed insert diameters	33mm, 39 mm	36 mm, 42 mm	36 mm, 42 mm	32 mm, 36 mm, 40 mm
Method of fixation Glenoid components	Uncemented	Uncemented	Uncemented	Unknown
Terminal sterilization	Gamma	Gamma	Gamma	Unknown
Manufacturer	Tornier	Tornier	Tornier	DJO
K-number	pending	K122698	K030941,K050316, K061439,K081059, K100142, K140478	K041066,K051075, K092873,K112069, K140904

The indications for use, the materials, the manufacturing principle, the method of fixation, the packaging and the sterilization process of the pending reversed insert are identical or equivalent to the predicate devices.



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Aequalis Reversed Shoulder Prosthesis glenoid spheres :

Main features or system characteristics	Aequalis Reversed II (pending glenoid spheres)	Aequalis Reversed II (cleared glenoid spheres)	Surgical Reverse Shoulder Prosthesis (RSP spheres)
Material	Titanium, CoCr	Titanium, CoCr	CoCr
Glenoid sphere diameters	33mm, 39mm	36mm, 42mm	32 mm, 36mm, 40 mm
Method of fixation with the base plate	Taper + Glenoid sphere Screw	Taper + Glenoid sphere Screw	Taper + Glenoid sphere Screw
Method of fixation glenoid components	Uncemented	Uncemented	Unknown
Terminal sterilization	Gamma	Gamma	Unknown
Manufacturer	Tornier	Tornier	DJO
K-number	Pending	K030941, K050316, K061439, K081059, K100142, K140478	K041066, K051075, K092873, K112069, K140904

The indications for use, the materials, the manufacturing principle, the method of fixation, the packaging and the sterilization process of the pending glenoid spheres are identical or equivalent to the predicate devices.

10) Non-clinical testing

NA

11) Substantial conclusion equivalence

Based upon this comparative study, substantial equivalence of the new *Aequalis™ Ascend™ Flex* reversed inserts and the new *Aequalis Reversed* glenoid spheres to the predicates can be demonstrated on the following grounds, according to the FDA's Guidelines for Substantial Equivalence Decision Making Process:

- The new *Aequalis™ Ascend™ Flex* reversed inserts and the new *Aequalis Reversed II* glenoid spheres are compared to the predicate devices.
- The new *Aequalis™ Ascend™ Flex* reversed inserts and the new *Aequalis Reversed II* glenoid spheres have the same intended use as the cleared predicates and have very similar indications for use.
- Major technological characteristics are equivalent between new *Aequalis™ Ascend™ Flex* reversed inserts and their predicate devices and the new *Aequalis Reversed* glenoid spheres and their predicate devices:
 - Equivalence of general features
 - Equivalent materials,
 - Equivalent biomechanical features: mechanical characteristics, congruence of articular surfaces,
 - Equivalent means of fixation
 - Equivalent prosthetic dimensions

Therefore, in light of the above information, the new *Aequalis™ Ascend™ Flex* reversed inserts and the new *Aequalis Reversed II* glenoid spheres are found to be equivalent to their predicate devices respectively.



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