June 12, 2019

Tornier SAS
Lamia Askri
Regulatory Affairs Specialist
161 rue Lavoisier
38330 Montbonnot Saint Martin
France

Re: K190521
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: KWS, KWT, HSD, PHX
Dated: May 6, 2019
Received: May 13, 2019

Dear Lamia Askri:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For: CAPT Raquel Peat, PhD, MPH, USPHS
Director
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190521

Device Name
Aequalis™Ascend™Flex Shoulder System

Indications for Use *(Describe)*

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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Summary of Safety and Effectiveness information
Special 510(k) Premarket – Aequalis Ascend Flex Shoulder System

Regulatory authority: Safe Medical Devices Act of 1990, 21 CFR 807.92
Date Prepared: February 28,2019

Administrative Information

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Device Information

Name of Device:	Aequalis™ Ascend™ Flex Shoulder System
Common Name (s):	Shoulder Prosthesis
Regulatory Class:	Class II
Regulation:	21 CFR § 888.3660, Shoulder joint metal/polymer semi-constrained cemented prosthesis.
Product Codes:	KWS, KWT, HSD, PHX

Predicate Device Information

Predicate:	Aequalis™ Ascend™ Flex Shoulder System
510(k) Number:	K122698, K151293

Device Description:

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 System* 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 arthroplasty. 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) 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.

This submission corresponds to the addition of 135° & 140° reversed final angle combinations and the Inlay technique, in addition to the existing 145° angle without any change in the implants design.

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.

Indications For Use

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.

Comparison of Technological Characteristics with the Predicate Device

The proposed changes to the predicate device include the addition of 135° & 140° reversed final angle and an alternate surgical option (Inlay), in addition to the existing 145° angle. These changes consist of added stem/ insert combinations without any change in the implants design. The subject device has the same design of implants, the same materials, the same manufacturing principle, the same method of fixation, the same packaging and the same sterilization process as the predicate device.

The new combinations do not raise new issues of safety or effectiveness and are supported by performance testing.

Non-clinical Performance Testing

Non-clinical bench testing and process validations were performed to demonstrate substantial equivalence of the subject device to the predicate device.

- Fatigue test in anatomic and reversed configuration

Clinical Testing

Clinical studies were not required to demonstrate substantial equivalence between the subject device and the predicate device.

Conclusions

The Aequalis™ Ascend™ Flex Shoulder System does not raise new questions of safety or effectiveness. with performance testing. The results of performance testing for the new angle combinations of the Aequalis Ascend Flex Shoulder System support substantial equivalence to the current Aequalis Ascend Flex Shoulder System (K122698, K151293).