



Food and Drug Administration
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Tornier S.A.S.
Ms. Jovila Dodi
Regulatory Affairs Specialist
161, rue Lavoisier
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FRANCE

January 14, 2016

Re: K152966
Trade/Device Name: Aequalis Fx2
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder Joint Metal/Polymer Semi-Constrained Cemented Prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, HSD
Dated: October 2, 2015
Received: October 7, 2015

Dear Ms. Dodi:

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 Parts 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,

Mark N. Melkerson -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K152966

Device Name

Aequalis Fx2

Indications for Use (Describe)

IN ANATOMIC:

The Aequalis Fx2 humeral stem combined with the Flex Shoulder System humeral 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 Fx2 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 Fx2 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 proximal humerus except for size 50mm(1)
- Traumatic arthritis
- Revision of other devices if sufficient bone stock remains except for size 50mm(1)

IN REVERSE:

The Aequalis Fx2 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 proximal humerus except for size 50mm(1)
- Traumatic arthritis
- Revision of the devices if sufficient bone stock remains except for size 50mm(1). The reversed insert is permitted to be used in the transformation from anatomic to reverse Aequalis Fx2 without the removal of the humeral stem, and if it is well fixed, during a revision surgery, for patient with a functional deltoid muscle.

Notes:

- all components are single use.
- the humeral stem is for cemented use only, except for size 50mm which is for uncemented use only(1).
- 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
- the humeral head diameters 37 and 39mm must be utilized only with the stem with a small metaphysis. The humeral head must cover completely the stem metaphysis .

(1) The 50mm length of the Aequalis Fx2 stem is not available for sale within the United States.

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.

Summary of Safety and Effectiveness information

Special 510(k) Premarket – Aequalis Fx2

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

Date: January 5th, 2016

1) Device name

Trade name : *Aequalis Fx2*

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) 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 PHX)
- 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 :

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38330 Montbonnot Saint Martin-France
Registration Number: 3000931034

3) Company contact :

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4) Classification

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

5) Equivalent / Predicate device :

Aequalis Fx2, TORNIER SAS, K141345
Aequalis Reversed, TORNIER SAS, K030941

6) Device description :

The *Aequalis Fx2* is a non-constrained prosthesis intended for the total or partial replacement of the gleno-humeral articulation.

The *Aequalis Fx2* consists of:

- in an anatomic configuration, a humeral stem compatible with Flex Shoulder System humeral heads (K122698 ; K140082);

or

- in a reversed configuration, a humeral stem and a reversed insert, compatible with *Aequalis*



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S.A.S. au capital de 35 043 008 €
SIRET : 070 501 275 000 21
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CODE APE : 3250 A

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Reversed/Aequalis Reversed II glenoid implants (K081059; K140478).

The *Aequalis Fx2* is intended for use as:

- traumatic or pathologic conditions of the shoulder resulting in fracture of the glenohumeral joint, including humeral head fracture and displaced 3-or 4-part proximal humeral fractures,
- in case of bone defect in the proximal part of the humerus,
- 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 Fx2* also allows for conversions from anatomic to reverse shoulder prosthesis in case of revision.

This submission corresponds to the design modification related to the Aequalis Fx2 assembly zone (humeral stems and reversed inserts) compatible only with each other. This design modification does not affect the intended use of the device or alter the fundamental scientific technology of the device. The pending humeral stems are compatible with the cleared Flex Shoulder humeral heads and the pending reversed inserts are compatible with the cleared Aequalis Reversed/Aequalis Reversed II glenoid implants. There is no change regarding the material of the pending Aequalis Fx2 humeral stems. The design change related to the pending Aequalis Fx2 reversed inserts does not include a titanium locking ring in contrast to the previously cleared Aequalis Fx2 reversed inserts.

7) Materials :

The material of the pending humeral stem does not change. The humeral stem, is manufactured from titanium alloy (Ti6Al4V) and coated with hydroxylapatite (HAP).

The modified design of the reversed insert does not include the titanium locking ring. The pending reversed insert is manufactured only from UHMWPE (Ultra High Weight Polyethylene).

8) Indications :

IN ANATOMIC:

The Aequalis Fx2 humeral stem combined with the Flex Shoulder System humeral 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 Fx2 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 Fx2 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 proximal humerus
- Traumatic arthritis
- Revision of other devices if sufficient bone stock remains

IN REVERSE:

The Aequalis Fx2 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 proximal humerus
- Traumatic arthritis
- Revision of the devices if sufficient bone stock remains. The reversed insert is permitted to be used in the transformation from anatomic to reverse Aequalis Fx2 without the removal of the humeral stem, and if it is well fixed, during a revision surgery, for patient with a functional deltoid muscle.



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Notes:

- all components are single use.
- the 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
- the humeral head diameters 37 and 39mm must be utilized only with the stem with a small metaphysis. The humeral head must cover completely the stem metaphysis .

9) Summary of technological characteristics

The pending Aequalis Fx2 humeral stem and reversed insert have the same intended use and fundamental scientific technology as the predicate device (K141345). The indications for use, the manufacturing principle, the method of fixation, the packaging and the sterilization process of the pending humeral stems and reversed inserts are identical or equivalent to the predicate device (K141345). The design differences have been demonstrated to be comparable to the predicate devices (K141345). Consequently, this design change does not affect safety or effectiveness or raise new issues of safety or effectiveness of the prosthesis.

10) Performance Data

The following performance data were provided in support of the safety and effectiveness of this design change :

Table 1 : Performance Data

Validation and / or Verification Method	Acceptance Value / Criteria	Results
Dimensional comparison	The geometric shape of the reversed insert articular surface must be compatible with the existing range of <i>Aequalis</i> Reversed/Reversed II glenoid spheres	Acceptable
Assembly method	Assembly method between pending Aequalis Fx2 (reversed insert and humeral stems) must be equivalent to the assembly method between cleared Aequalis Fx2 (reversed insert and humeral stems)	Acceptable
Convertibility	The assembly geometry of the humeral stem must allow the conversion from the anatomical configuration to the reversed configuration of the prosthesis	Acceptable
Dimensional comparison	The external geometric shape of the pending Aequalis Fx2 humeral stem must be the same as the cleared Aequalis Fx2 humeral stem	Acceptable
Fatigue testing	No failure after the test	Acceptable
Pull out pre-fatigue testing	Equivalent to the predicate (K030941)	Acceptable
Torque testing	Equivalent to the predicate (K141345)	Acceptable
Pull out post fatigue testing	Equivalent to the predicate (K030941) before fatigue	Acceptable



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11) Substantial conclusion equivalence

Based upon this comparative study, substantial equivalence of the pending humeral stem and reversed insert *Aequalis Fx2* to the predicates can be demonstrated on the following grounds, according to the FDA's Guidelines for Substantial Equivalence Decision Making Process:

- The pending humeral stem and reversed insert *Aequalis Fx2* are compared to the predicate devices.
- The pending humeral stem and reversed insert *Aequalis Fx2* have the same intended use and indications for use as the cleared predicate.
- Major technological characteristics are equivalent between pending *Aequalis Fx2* humeral stem and reversed insert and their predicate device :
 - 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 pending *Aequalis Fx2* humeral stem and reversed insert are found to be equivalent to their predicate devices.

Consequently, this design change does not affect safety or effectiveness or raise new issues of safety or effectiveness of the prosthesis.



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