DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 18, 2014

TORNIER S.A.S.
Maud Andriollo
Regulatory Affairs Specialist
161 rue Lavoisier
38330 Montbonnot
Saint Martin
FRANCE

Re: K141345
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 28, 2014
Received: October 30, 2014

Dear Maud Andriollo:

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)*

K141345

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
- 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.

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.

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)*

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510 (k) Summary of Safety and Effectiveness information
Traditional 510(k) Premarket – Aequalis Fx2

Date: November, 14th 2014

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 :

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

3) Company contact :

Tornier
Mrs Maud Andriollo
Regulatory Affairs Specialist
161 rue Lavoisier
38334 Montbonnot
Tel: 00 33 4 76 61 35 00
Fax: 00 33 4 76 61 35 59
e-mail : maud.andriollo@tornier.com

4) Classification

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

5) Equivalent / Predicate device :

Aequalis Ascend Flex Shoulder System, TORNIER SAS, K122698

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Aequalis Shoulder Fracture System, TORNIER SAS, K060209, K131231
Aequalis Reversed Fracture Shoulder Prosthesis, TORNIER SAS, K082120, K131231
Comprehensive Reverse Shoulder System, BIOMET, K113069

6) Device description :

The *Aequalis Fx2* is a non-constrained prosthesis intended for the total or partial replacement of the glenohumeral articulation.
The *Aequalis Fx2* consists of:
- in an anatomic configuration, a humeral stem compatible with Flex Shoulder System humeral heads ;

or
- in a reversed configuration, a humeral stem and a reversed insert, compatible with Aequalis Reversed/Aequalis Reversed II glenoid implants.

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.

7) Materials :

The humeral stem is manufactured from titanium alloy (Ti6Al4V) in accordance with ISO 5832-3 and coated with hydroxylapatite (HAP) in accordance with ASTM standard F-1185 or ISO 13779-2.
The reversed insert is manufactured from UHMWPE according to ISO standard 5834-2 and titanium alloy (Ti6Al4V) in accordance with ISO 5832-3.

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.

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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.

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.

TORNIER S.A.S.
161, rue Lavoisier
38334 MONTBONNOT CEDEX
FRANCE

Tél. : 33 (0)4 76 61 35 00
Fax : 33 (0)4 76 61 35 33

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

SIEGE SOCIAL 161, rue Lavoisier - 38330 MONTBONNOT SAINT MARTIN – FRANCE

9) Summary of technological characteristics

Table 1: Main features comparison

Main features or system characteristics		Aequalis Fx2	Aequalis Ascend Flex Shoulder System	Aequalis Shoulder Fracture System	Aequalis Reversed Fracture Shoulder Prosthesis	Comprehensive Reverse Shoulder System
Material	Stem	Titanium + HAP	Titanium + Ti Plasma Spray	Titanium + HAP	Titanium + HAP	Titanium + Ti Porous Plasma spray
	Reversed Insert	UHMWPE + Titanium	UHMWPE + Titanium	NA	UHMWPE	Titanium + UHMWPE
Standard	Stem	ASTM F136 / ISO 5832-3	ASTM F136 / ISO 5832-3	ASTM F136 / ISO 5832-3	ASTM F136 / ISO 5832-3	unknown
	Coating	ASTM F1185	ASTM F1580	ASTM F1185	ASTM F1185	ASTM F1580
	Reversed Insert	ISO 5834-2 + ISO 5832-3	ISO 5834-2 + ISO 5832-3	NA	ISO 5834-2	unknown
Stem fixation		Cemented on distal part Uncemented on proximal part	Cemented or uncemented	Cemented on distal part Uncemented on proximal part	Cemented use	Cemented or uncemented
Stem length		90; 130; 170; 210 mm	66; 70; 74; 78; 82; 86; 88; 90; 93; 94; 98; 104; 109; 115; 120; 125 mm	130; 170; 180; 210 mm	130; 170; 180; 210 mm	55; 83; 122; 194 mm
Diameter of reversed insert		36mm, 42mm Thickness 6; 9; 12 mm	36mm, 42mm Thickness 6; 9 mm	NA	36mm, 42mm Thickness 6; 9; 12mm	31mm, 36mm, 41mm
Terminal sterilization		Yes	Yes	Yes	Yes	Yes
Manufacturer		Tornier	Tornier	Tornier	Tornier	Biomet
K-number		Pending	K122698	K060209, K131231	K082120, K131231	K113069

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The design, the indication for use, the material, the manufacturing principle, the method of fixation of the stem, the packaging and the sterilization process of the *Aequalis Fx2* are identical or equivalent to the predicate devices.

10) Non-clinical testing

Pull out, torque testing, and fatigue testing were performed.

- The aim of pull out and torque testing is to validate the locking mechanism between a metal part simulating an *Aequalis Fx2* humeral stem and an UHMWPE simulating reversed insert.
- The aim of fatigue testing in anatomic configuration is to evaluate the fatigue strength of the *Aequalis Fx2* implant in an anatomic configuration.
- The aim of fatigue testing in reversed configuration is to evaluate the fatigue strength of the *Aequalis Fx2* implant in a reversed configuration after anatomic configuration.

The results of these tests demonstrate the equivalence between the *Aequalis Fx2* and the predicate devices.

11) Substantial equivalence conclusion

Based upon this comparative study, substantial equivalence of the *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 *Aequalis Fx2* is compared to the predicate devices.
- The *Aequalis Fx2* has the same intended use as the cleared predicates.
- Major technological characteristics are equivalent between the *Aequalis Fx2* and the predicate devices:
    - Equivalence of general features
    - Equivalent means of fixation
    - Equivalent material
    - Equivalent prosthetic dimensions

Therefore, in the light of the above information, the *Aequalis Fx2* is found to be equivalent to the predicate devices.