DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 2, 2016

Tornier SAS
Ms. Magalie Hennequin
Regulatory Projects Manager
161 rue Lavoisier
38330 Montbonnot Saint Martin
FRANCE

Re: K140478
Trade/Device Name: Aequalis Reversed Shoulder Prosthesis
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS
Dated: July 4, 2014
Received: July 7, 2014

Dear Ms. Hennequin:

This letter corrects our substantially equivalent letter of August 6, 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

Indications for Use

510(k) Number (if known):
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 non-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 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 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.

Prescription Use X	AND/OR	Over-The-Counter Use
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510 (k) Summary of Safety and Effectiveness information
Traditional 510(k) Premarket – Aequalis Reversed Shoulder Prosthesis

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

1) Device name

Trade name: *AEQUALIS Reversed Shoulder Prosthesis*
Common name: Shoulder Prosthesis
Classification name: Shoulder joint metal/polymer semi-constrained cemented prosthesis

2) Submitter :

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

3) Company contact :

Tornier
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4) Classification

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

5) Equivalent / Predicate device :

Aequalis Reversed Shoulder Prosthesis – CoCr Glenosphere, TORNIER SAS, K030941, K061439, K081059, K100142
Comprehensive Reverse Shoulder – Titanium Glenosphere, BIOMET, K131353

6) Device description :

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. In this case, the rotator muscles of the shoulder (supraspinatus, infraspinatus, teres minor and long head of the biceps) are no more useful for mobility, and only the deltoid (for abduction and external rotation) and the subscapularis (for internal rotation) are functional.
Therefore, the usual goal of such surgery is to restore the shoulder joint to facilitate its working condition and to reduce or eliminate pain. The *Aequalis Reversed Shoulder Prosthesis* is intended to accomplish these goals. Its reversed design allows to medialize the center of rotation of the shoulder, lengthening the deltoid muscle lever arm.

The *Aequalis Reversed Shoulder Prosthesis* is a semi-constrained system composed of a humeral and a glenoid parts.

The present device modification submission consists in the addition of glenoid sphere in Titanium.

7) Materials :

The glenoid sphere is manufactured from Titanium alloy.

8) Indications :

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 non-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 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 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

Table 1: Main features comparison

Main features or system characteristics		**Aequalis Reversed II Shoulder System** (new components – Titanium glenosphere)	**Aequalis Reversed II Shoulder System** – CoCr Glenosphere	**Comprehensive** - Titanium Glenosphere	SE?
Material		Titanium	CoCr	Titanium	Yes
Standard		ASTM F136 / ISO 5832-3	ISO 5832-12 ou ISO 5832-7	-	Yes
Method of fixation with the base plate		Taper + Glenoid sphere Screw	Taper + Glenoid sphere Screw	Taper + Glenoid sphere Screw	Yes
Diameter of glenoid sphere	Centered	36mm, 42mm	36mm, 42mm	36mm, 41mm	Yes
	Tilted	36mm, 42mm Excentration +2mm	36mm, 42mm Excentration +2mm	-	Yes
	Off-centered	36mm, 42mm Lateralization +4mm	36mm, 42mm Lateralization +4mm	36mm, 41mm Lateralization +3mm, +6mm	Yes
Terminal sterilization		Yes	Yes	Yes	Yes
Manufacturer		Tornier	Tornier	Biomet	-
K-number		Pending	K030941, K061439, K081059, K100142	K131353	-

The design, the indication for use, the material, the manufacturing principle, the method of fixation of the new sphere on the base plate and the sterilization process are not modified for the pending glenoid sphere to the predicate.

10) Non-clinical testing

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

- The aim of pull out testing is to show the equivalence between the new Aequalis Reversed glenoid sphere and the cleared models independently of the material.

To demonstrate the equivalence between the new glenoid sphere and the cleared glenoid sphere the resistance in Pull-out has to be equivalent.

- The aim of fatigue testing is to evaluate the behavior of the new Aequalis Reversed glenoid sphere and cleared baseplate assembly.

To evaluate the behavior of the new glenoid sphere no relative motion and no disassembly have to be observed.

- The aim of wear testing is to compare the new Aequalis Reversed glenoid sphere in Titanium and the cleared models in Cocr wear characterictics when facing a UHMWPE material.

To demonstrate the equivalence between the new glenoid sphere and the cleared glenoid sphere the wear characterictics have to be equivalent in terms of: weight loss, wear rate and shape and size of the particles generated.

The results of these tests demonstrate the equivalence between the new Aequalis Reversed glenoid sphere and the cleared Aequalis Reversed glenoid sphere.

11) Substantial equivalence conclusion

Based upon this comparative study, substantial equivalence of the new glenoid sphere of the Aequalis Reversed II Shoulder Prosthesis to the predicate can be demonstrated on the following grounds, according to the FDA's Guidelines for Substantial Equivalence Decision Making Process:

- The new glenoid sphere of the Aequalis Reversed II Shoulder Prosthesis is compared to the predicate devices.
- The new glenoid sphere of the Aequalis Reversed II Shoulder Prosthesis has the same intended use as the cleared glenoid sphere of the Aequalis Reversed II Shoulder Prosthesis.
- Major technological characteristics are equivalent between the new glenoid sphere of the Aequalis Reversed II shoulder prosthesis 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 new glenoid sphere of the Aequalis Reversed II Shoulder Prosthesis is found to be equivalent to the predicate devices