Tornier, Inc.
Laurie Lewandowski
Regulatory Associate, Consultant
10801 Nesbitt Ave South
Bloomington, Minnesota 55437

September 20, 2018

Re: K181420
Trade/Device Name: Aequalis Flex Revive 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, PHX, HSD
Dated: August 30, 2018
Received: August 31, 2018

Dear Laurie Lewandowski:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Vesa Vuniqi -S

Digitally signed by Vesa Vuniqi -S
Date: 2018.09.20 16:24:14 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181420

Device Name
Aequalis Flex Revive Shoulder System

Indications for Use *(Describe)*

IN ANATOMIC:

The proximal body, stem, assembly screw, locking cap, optional spacer(s), and humeral head may be used together, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement.

The AEQUALIS FLEX REVIVE 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 FLEX REVIVE 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 FLEX REVIVE Shoulder System is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle 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
- Massive and non-repairable rotator cuff tear
- Revision of the devices if sufficient bone stock remains

The reversed tray and polyethylene insert are indicated for use in the conversion from an anatomic to reversed shoulder arthroplasty without the removal of the humeral assembly during revision surgery for patients with a functional deltoid muscle.

Notes:
- All components are single use.
- The coated humeral stem is intended for cemented or cementless use.
- 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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Date Prepared: May 30, 2018

K181420

Administrative Information

Name: Tornier, Inc.
Address: 10801 Nesbitt Avenue South
Bloomington, MN 55437
United States of America

Contact Person: Laurie Lewandowski
Title: Regulatory Associate, Contract
Phone: 612-770-4038
Fax: 952-426-7601

Device Information

Name of Device: AEQUALIS FLEX REVIVE Shoulder System
Common Name (s):
Classification Name: Prosthesis, Shoulder, Semi-Constrained, Metal/ Polymer Cemented
Regulatory Class: II
Regulation Number: 888.3660, 888.3690
Product Code: KWS, PHX, HSD

Predicate Device Information

Predicate Device: Aequalis Ascend Flex Shoulder System
510K number: K140082
Reference Device: Aequalis Adjustable Reversed Shoulder System
510K Number: K141029

Device Description

AEQUALIS FLEX REVIVE Shoulder System (AFR) is a fully convertible anatomic and reversed shoulder arthroplasty system that is designed to be used with existing Tornier implant systems. It is a non-constrained system intended for total or partial replacement of the glenohumeral articulation. AFR includes a proximal body (metaphysis), spacer(s), a stem, assembly screw, and locking cap. The proximal body has a female taper that is compatible with Ascend Flex Humeral Head and Ascend Flex reversed trays and poly inserts.

The AFR Shoulder System is implanted by a surgeon and is designed to allow the surgeon to select the components to size the shoulder system for the patient. It allows the shoulder to be constructed in an anatomical or reversed configuration using cleared Ascend Flex humeral heads or Ascend Flex reversed trays and inserts. In addition, the AFR Shoulder System can be transformed from anatomic to reverse shoulder prosthesis without the removal of the humeral implant assembly during revision surgery.

The humeral length is measured to determine the overall humeral implant construct length. The length is assembled from 120 mm (using the short proximal body and stem) to 180 mm (using the standard proximal body, spacers, and stem) in 10mm increments with the spacers as needed and either of the two available lengths of the proximal body for patient specificity.

The proximal body, stem, and spacers are made from Ti6Al4V per ASTM F-136. The proximal body and stem have a Titanium plasma coating. The assembly screw and locking cap are made from of CoCr per ISO 5832-12l. They are single use and packaged sterile, using gamma radiation at a minimum dose of 25 KGy to an SAL of $1x10^{-6}$.

The AFR Shoulder System is comprised of the component in Table 5.1.

Table 5. 1 AFR Shoulder System Components

Catalog #	Description	Diameter (mm)	Effective Length (mm)	Angle (º)
Proximal Body				
ARS741701	Proximal Body	Ø9	40	132.5
ARS741702	Proximal Body	Ø11	40	132.5
ARS741703	Proximal Body	Ø13	40	132.5
ARS741704	Proximal Body	Ø15	40	132.5
ARS741705	Proximal Body	Ø17	40	132.5
ARS741706	Proximal Body	Ø19	40	132.5
ARS741707	Short Proximal Body	Ø9	30	132.5
ARS741708	Short Proximal Body	Ø11	30	132.5
ARS741709	Short Proximal Body	Ø13	30	132.5
ARS741710	Short Proximal Body	Ø15	30	132.5
ARS741711	Short Proximal Body	Ø17	30	132.5
ARS741712	Short Proximal Body	Ø19	30	132.5
Spacers				
Catalog #	**Description**	**Size (diam. and length mm)**		
ARS342001	Spacer	Ø9 x 20		
ARS342002	Spacer	Ø11 x 20		
ARS342003	Spacer	Ø13 x 20		
ARS342004	Spacer	Ø15 x 20		
ARS342005	Spacer	Ø17 x 20		
ARS342006	Spacer	Ø19 x 20		
ARS342007	Spacer	Ø9 x 30		
ARS342008	Spacer	Ø11 x 30		
ARS342009	Spacer	Ø13 x 30		
ARS342010	Spacer	Ø15 x 30		
ARS342011	Spacer	Ø17 x 30		
ARS342012	Spacer	Ø19 x 30		

Tornier AEQUALIS FLEX REVIVE Shoulder System

Distal Stem			
Catalog #	**Description**	**Diameter (mm)**	**Length (mm)**
ARS741801	Distal Stem	Ø9	90
ARS741802	Distal Stem	Ø11	90
ARS741803	Distal Stem	Ø13	90
ARS741804	Distal Stem	Ø15	90
ARS741805	Distal Stem	Ø17	90
ARS741806	Distal Stem	Ø19	90
Assembly Screw			
Catalog #	**Description**	**Effective Length (mm)**	
ARS655101	Assembly Screw	0	
ARS655102	Assembly Screw	20	
ARS655103	Assembly Screw	30	
ARS655104	Assembly Screw	40	
ARS655105	Assembly Screw	50	
ARS655118	Assembly Screw, Short	0	
ARS655119	Assembly Screw, Short	20	
Locking Cap			
Catalog #	**Description**		
ARS655200	Locking Cap		

Intended Use

The AEQUALIS FLEX REVIVE Shoulder System is intended for replacement of the shoulder joint to reduce pain and improve shoulder mobility in comparison with preoperative status.

Indications for Use

IN ANATOMIC:

The proximal body, stem, assembly screw, locking cap, optional spacer(s), and humeral head may be used together, as a hemiarthroplasty, if the natural glenoid provides a sufficient bearing surface, or in conjunction with the glenoid, as a total replacement.

The AEQUALIS FLEX REVIVE 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 FLEX REVIVE 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 FLEX REVIVE Shoulder System is indicated for use as a replacement of shoulder joints for patients with a functional deltoid muscle 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
- Massive and non repairable rotator cuff tear
- Revision of the devices if sufficient bone stock remains

The reversed tray and polyethylene insert are indicated for use in the conversion from an anatomic to reversed shoulder arthroplasty without the removal of the humeral assembly during revision surgery for patients with a functional deltoid muscle.

Notes:
- All components are single use.
- The coated humeral stem is intended for cemented or cementless use.
- 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.

Comparison of Technological Characteristics with the Predicate Device

Table 5.2 compares the technological characteristics of the AFR shoulder System to the predicate, Aequalis Ascend Flex and the reference device, Aequalis Adjustable Reversed as applicable.

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Table 5. 2 Comparison of Technological Characteristics

	Aequalis Flex Revive Shoulder System (AFR)	Predicate Ascend Flex (K140082) Reference Device Adjustable Reversed (K141029)
Design Principal	Modular design to allow the surgeon to select the components to size the shoulder system for the patient; convertible from anatomic to reversed without removing the implant assembly	Ascend Flex – multiple sizes for surgeon selection; convertible from anatomic to reversed without removing the implant assembly. Adjustable Reverse – modular design to allow surgeon to select the components to size the shoulder system for the patient.
Overall lengths	Adjustable total lengths from 120mm to 180mm (10mm increments)	Ascend Flex - 66mm to 98mm (standard coated) 88mm to 130mm (long coated) 66mm to 94mm (standard non-coated) 88mm to 125mm (long non-coated) Adjustable Reverse – adjustable length, using spacers, up to 210mm
Stem and Spacer Diameters (diaphysis)	9, 11, 13, 15, 17, 19 mm	Ascend Flex- Standard Stems: 9 – 20mm Long Stems: 9 – 20mm Adjustable Reverse - 9, 11, 13, 15, 17mm
Spacer length	20, 30 mm	Ascend Flex - N/A Adjustable Reversed - 15, 20, 25, 50, and 100mm
Materials	Proximal body, spacers, distal stems: Titanium alloy (Ti6Al4V) and commercially pure Ti (coating) Assembly Screw and Locking Cap: CoCr	Titanium alloy (Ti6Al4V) and commercially pure Ti (coating)
Sterility Assurance Level (SAL)	$1x10^{-6}$	Identical
Sterilization Method	Gamma	Identical

Non-clinical Performance Testing

Table 5.3 is a summary of the testing performed on the AEQUALIS FLEX REVIVE Shoulder System.

Table 5. 3 Summary of the Testing Performed on the AFR Shoulder System

Test Performed	Acceptance Criteria
Fatigue Testing	The humeral stems were tested to 10 million cycles (5 million in each configuration) without failure, fracture, or dislocation when inspected after each tested configuration at a magnification of 50X.
Range of Motion	The Aequalis Flex Revive Shoulder System met the range of motion requirements in ASTM F1378-12.
Taper Tensile	Taper resultant force were not significantly lower than those of the Ascend Flex taper connections when analyzed with a 2-sample T-test.
Tensile Static Torque	The disassociation torque of the male taper from the female taper was not statistically lower than 1.72Nm, or two times the anticipated frictional torque between glenoid sphere and the reversed insert.
Press Fit Preparation	The AFR Shoulder System achieved a press-fit for the proximal body and distal stem allowing the implant to attain proper seating and acceptable fixation.
Cemented Preparation	The AFR Humeral Stem cement mantle thickness met or exceeded the Ascend Flex cement mantle thickness.
Biocompatibility	Biocompatibility requirements per ISO 10993-1 were met
Endotoxin	Endotoxin results per ST72 demonstrated <20EU/device
Packaging	Distribution testing met requirements per ASTM D4169-16

Conclusions

The AEQUALIS FLEX REVIVE Shoulder System has similar intended use and indications for use as the predicate, Ascend Flex Shoulder System (K140082). The reference device supports the use of the spacers to allow the surgeon to select the implant construct length for the patient. Testing demonstrated the AFR met the test requirements and compares favorably to the predicate. The AFR Shoulder System is substantially equivalent to the Ascend Flex Shoulder System.