DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 4, 2015

Tornier, Incorporated
Ms. Loucinda Bjorklund
Principal Regulatory Affairs Project Manager
10801 Nesbitt Avenue South
Bloomington, Minnesota 55437

Re: K143552
Trade/Device Name: Simpliciti™ Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PKC
Dated: December 12, 2014
Received: December 15, 2014

Dear Ms. Bjorklund:

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): K143552

Device Name: Simpliciti™ Shoulder System

Indications for Use:
The Simpliciti™ Shoulder System is indicated for severely painful and/or disabled joint resulting from osteoarthritis or traumatic arthritis.

The metaphyseal humeral stems are indicated for press-fit, un-cemented use.

The glenoid components are indicated for cemented use only and are indicated only for use with bone cement.

This device is for single use.

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

Date Prepared: February 28, 2015

I. Administrative Information

Name:	Tornier, Inc.
Address:	10801 Nesbitt Avenue South Bloomington, MN 55437
Contact Person:	Loucinda Bjorklund Principal Regulatory Affairs Project Manager
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II. Device Information

Name of Device:	Simpliciti™ Shoulder System
Common Name:	Shoulder Prosthesis
Classification Name:	21 CFR 888.3660, shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class:	Class II
Product Code:	PKC

III. Predicate Device Information

Affiniti Shoulder System, K103007

IV. Device Description

The Simpliciti™ Shoulder System is intended for use in Total Shoulder Arthroplasty of the shoulder (TSA) application. As a Total shoulder, the system consists of a metaphyseal metal humeral component, a metal humeral head and an ultrahigh molecular weight polyethylene glenoid. Glenoid components are labeled "for cemented use only" and are indicated only for use with bone cement. The metaphyseal humeral components are indicated and labeled for press-fit un-cemented use.

The materials used in the manufacture of the Simpliciti™ Shoulder System implants are as follows:

- Metaphyseal humeral component is made of titanium alloy (Ti-6AL-4V) in accordance to ASTM standard F136 with a sintered titanium (CP Ti) bead coating conforming to ASTM F-1580.
- The humeral heads are made off cobalt-chromium- alloy (CoCr) according to ASTM standard F1537.
- The glenoid components are made of ultrahigh molecular weight polyethylene (UHMWPE) according to ASTM standard F648 or ISO 5834-2.

V. Intended Use

The Simpliciti™ Shoulder System is intended for Total Shoulder Arthroplasty

VI. Indications for Use

The Simpliciti Shoulder System is indicated for severely painful and/or disabled joint resulting from osteoarthritis or traumatic arthritis.

The metaphyseal humeral stems are indicated for press-fit, un-cemented use.

The glenoid components are indicated for cemented use only and are indicated only for use with bone cement.

This device is for single use.

VII. Comparison of Technological Characteristics with the Predicate Device

The Simpliciti Shoulder System has the same intended use and fundamental scientific technology as the predicate device. The Simplicit Shoulder System has the same intended use and fundamental scientific technology as the predicate device. The technological characteristics (material, design, sizing, indications, coating, packaging, shelflife, and sterilization) of the Simpliciti Shoulder System are substantially equivalent to the predicate device. The design differences have been demonstrated to not affect safety or effectiveness or raise new issues of safety or effectiveness.

Characteristic	Simpliciti Shoulder System (Subject Device)	Affiniti Shoulder System (Predicate Device) K103007
510(k) Number	To be assigned	K103007
Device Class	Class II	
Device Code	KWS	KWS, HSD
Regulation Classification	21 CFR 888.3660	21 CFR 888.3660, 21 CFR 888.3690
Intended Use	The Simpliciti Shoulder System is intended for total shoulder arthroplasty of the shoulder.	The Affiniti Shoulder System is intended for use as a total or hemi-shoulder system.
Indications for Use	The Simpliciti Shoulder System is indicated for severely painful and/or disabled joint resulting from osteoarthritis and traumatic arthritis. The metaphyseal humeral stems are indicated for press-fit, un-cemented use. The glenoid components are indicated for cemented use only and are indicated only for use with bone cement. This device is for single use.	The Affiniti Total and Hemi-Shoulder System is indicated for: • A severely painful and / or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis; • Fracture / dislocations of the proximal humerus; where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative

Characteristic	Simpliciti Shoulder System (Subject Device)	Affiniti Shoulder System (Predicate Device) K103007
		methods of treatment are unsatisfactory; • Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g., revision of a failed primary component). The Affiniti Hemi-Shoulder System is also indicated for: • Ununited humeral head fractures • Avascular necrosis of the humeral head • Rotator cuff tear arthropathy Note: Glenoid components labeled for "cemented use only" and are indicated only for use with bone cement. Humeral stems are indicated for press-fit un-cemented use or for use with bone cement. This is a single use device.
Humeral Stem (Nucleus)		
Stem Component Material (Substrate)	Titanium alloy (Ti-6Al-4V): conforms to ASTM F-136 or ISO 5832-3	
Stem Design	Three fins that extend radially from the center and are equally spaced at 120°. Porous Coated	Single post with a stem diameter range from 6 mm to 18 mm Porous coated and uncoated.
Stem Lengths	18 mm to 24 mm	110 mm to 220 mm
Porous Coating Material	Sintered titanium bead coating conforms to ASTM F-1580 or ISO 5832-2	
Porous Coating Volume Porosity	30% to 70%	

Characteristic	Simpliciti Shoulder System (Subject Device)	Affiniti Shoulder System (Predicate Device) K103007
Porous Coating Average Pore Size	100 µm to 1000 µm	
Porous Coating Thickness	500 µm to 1500 µm	
Packaging	Packaged into a polyethylene sleeve and placed into a Tyvek / Mylar pouch. Pouch is sealed and placed into a secondary Tyvek / Mylar pouch. Secondary pouch is sealed and placed into a labeled carton box.	
Shelf Life	5 Years	
Sterilization	Gamma Irradiation	
Humeral Head		
Component Material	Cobalt Chrome conforms to ASTM F-1537, ISO 5832-7 or ISO 5832-12	
Diameter	39 mm to 56 mm	
Head Thickness	14 mm to 23 mm	
Packaging	Packaged in Double Tyvek pouch or a double foil pouch that is placed in an outer box and shrink wrapped.	
Shelf Life	5 Years	
Sterilization	Gamma Irradiation	
Glenoid		
Component Materials	Ultra high molecular weight polyethylene conforming to ASTM F-648	
Sizes Keeled Glenoid	40 XS, 40, 44, 48, 52, 56, 56XL	
Sizes Pegged Glenoid	40, 44, 48, 52, 56	
Packaging	Packaged in Double Tyvek pouch or a double foil pouch that is placed in an outer box and shrink wrapped.	
Shelf Life	5 Years	

VIII. Performance Data

Non-clinical performance bench testing (mechanical testing) was performed to demonstrate substantial equivalence to the predicate device.

Non-clinical Performance Testing Summary for Simpliciti Shoulder System

Validation and / or Verification Method	Acceptance Value / Criteria	Verification and Validation Results
CAD study to ensure acceptable geometry	Head geometry is comparable to the Aequalis humeral heads	Acceptable
Mechanical testing (fatigue)	The nucleus shall survive a prescribed number of cycles at a prescribed load without fatigue, fracture, yielding, loosening	Acceptable
Mechanical testing (lever out)	Qualitative Comparison to Aequalis Resurfacing Shoulder	Acceptable
Mechanical testing (pull out)	Qualitative Comparison to Aequalis Resurfacing Shoulder	Acceptable
Mechanical testing (torque out)	Qualitative Comparison to Aequalis Resurfacing Shoulder	Acceptable
Mechanical testing (taper disassociation testing)	The Simpliciti Shoulder taper is equivalent to the taper of the Affiniti Shoulder System	Acceptable
X-ray overlay validation	No impingement of the fin geometry on the inner cortex of the metaphysis	Acceptable

IX. Clinical Study

The Simpliciti Shoulder System study was a prospective, single arm, multi-center study conducted at 14 sites in the US which enrolled 157 subjects (181 consented and screened). The purpose of the Simpliciti IDE study was to demonstrate safety and effectiveness of the Simpliciti system in total shoulder arthroplasty at 24 months. Subject outcomes were compared to results of a historical control group with a primary diagnosis of osteoarthritis or traumatic arthritis and implanted with a FDA cleared, Tornier stemmed humeral prosthesis. A subject was a success at 24 months if: there was no continuous radiolucent line around the prosthesis, the adjusted Constant score was > 85, they did not have revision surgery, and they did not have a system-related serious adverse event. Secondary objectives included quality of life, range of motion, strength, and radiographic device assessment.

The percentage of subjects who met all four criteria is 88.74% with a lower one-sided 95% confidence bound of 83.59%. As the lower bound is greater than the percentage of success observed in the historic control (75% and the non-inferiority margin (10%), the null hypothesis is rejected in favor of the alternative hypothesis that the primary endpoint is greater than 75%.

All secondary QOL objectives, on average, reported patient improvement. Additionally, third party radiologists determined there were no instances of radiolucency, device migration, osteolysis, or subsidence of the glenoid component or nucleus.

There were 228 reported Adverse Events (AEs) occurring in 103 of the study subjects. Study investigators classified relatedness of all AEs as definitely related, possibly related, unknown relatedness, or not related to the study system or procedure. There were 22 (22/228, 9.6%) AEs in 21 subjects (21/157, 13.4%) that were considered related to the system or procedure. One (0.4%) AE for aseptic glenoid loosening was considered possibly related to the system. Ten (4.4%) events were reported as definitely related to the procedure and 11 (4.8%) were reported as possibly related to the procedure. Adverse events definitely related to the procedure included: infection (2), shoulder stiffness (2), paresthesia (2), ecchymosis (1), mental status changes (1), scarring (1), and keloid scar (1). Adverse events possibly related to the procedure included: paresthesia (4), weakness (2), tendonitis (1), pain (1), hematoma (1), arthrofibrosis (1), and osteoarthritis (1). All system or procedure related events were considered expected complications for total shoulder arthroplasty; thus, there were no Unanticipated Adverse Device Effects (UADEs).

There were a total of 55 reported serious AEs (SAEs). Three (3/55, 5.5%) SAEs were possibly (2/55, 3.6%) or definitely (1/55, 1.8%) related to the procedure and one (1/55, 1.8%) SAE was considered possibly related to the system. The aseptic glenoid loosening is the only SAE with a possible relationship to the system. The SAEs possibly related to the procedure included weakness (1) and arthrofibrosis (1) and the SAE definitely related to the procedure was an infection (1).

There were five subjects with revisions (3) and explants (2) of the Simpliciti system. The three revisions were for: nucleus upsize during initial implant (1), infection 4 weeks post-implant (1), and aseptic glenoid loosening 17 months post-implant (1). The two explants were for poor bone quality during the initial implant and subscapularis insufficiency 467 days post-implant.

The Simpliciti IDE study suggests that the Simpliciti system will perform equivalently to currently marketed shoulder devices for the treatment of osteo- and traumatic arthritis.

X. Conclusions

The Simpliciti Shoulder System described in this section has the same intended use and the same fundamental scientific technology as the cleared Affiniti Shoulder System. Based on the testing presented for the design differences between the subject and predicate devices, Tornier concludes that subject device is substantially equivalent to the predicate device.