



Food and Drug Administration
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November 2, 2016

DePuy (Ireland)
Ms. Kellie Myers
Regulatory Affairs Associate
Loughbeg
Ringaskiddy
County Cork, Ireland

Re: K133834

Trade/Device Name: DePuy Global UNITE Shoulder System
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: March 18, 2014
Received: March 19, 2014

Dear Ms. Myers:

This letter corrects our substantially equivalent letter of April 3, 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

Section 4: Indications for Use Statement

510(k) Number (if known): K133834

Device Name: DePuy Global UNITE Shoulder System

Indications for Use:

The Global UNITE Shoulder System humeral stems, suture collars, epiphyseal components and humeral heads are intended for cemented or uncemented total shoulder or hemi-shoulder replacement in treatment of the following:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis
2. 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 methods of treatment are unsatisfactory
3. Other difficult clinical problems where shoulder arthrodesis or resection arthroplasty are not acceptable (e.g. revision of a failed primary component)

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures
2. Avascular necrosis of the humeral head
3. Deformity and/or limited motion

When used in a total shoulder replacement, the Global Unite implants are to be used with DePuy glenoids. The glenoids are for cemented use only.

When well-fixed, the Global Unite humeral stems, in conjunction with existing Delta Xtend epiphyseal components, are also indicated for conversion to a reverse, in treatment of a grossly deficient rotator cuff joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary. The Delta Xtend metaglene is HA-coated and is intended for uncemented use with the addition of screws for fixation. The Delta Xtend epiphyseal components are HA-coated and are intended for uncemented use.

Prescription Use X AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(Please do not write below this line. Continue on another page if needed.)

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APR 03 2014



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Section 5: 510(k) Summary

(As required by 21 CFR 807.92 and 21 CFR 807.93)

NAME OF SPONSOR: DePuy (Ireland)
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Establishment Registration Number: 9616671

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DATE PREPARED: January 06, 2014

PROPRIETARY NAME: DePuy Global UNITE Shoulder System

COMMON NAME: Total and Hemi Shoulder Arthroplasty Prosthesis

CLASSIFICATION AND REGULATION: Shoulder joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3660, Product Code KWS)

Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (21 CFR 888.3690, Product Code HSD)

PREDICATE DEVICE: DePuy Global Advantage Humeral Stem with Porocoat, K011047
DePuy Global Advantage Shoulder, Global Advantage Humeral Stem, Global Advantage Eccentric Head, K992065



DEVICE DESCRIPTION

The subject devices expand the Global UNITE Shoulder System to include two additional cobalt-chrome alloy humeral heads that mate with existing Global UNITE epiphyseal bodies, as well as new porous-coated anatomic epiphyseal bodies made from titanium alloy that mate with existing Global UNITE humeral heads and stems. In the case of further deterioration of the joint or rotator cuff, the surgeon has the option to remove the Global UNITE anatomic epiphyseal component and replace it with a Delta Xtend Reverse (K120174) epiphyseal component for conversion to a reverse shoulder prosthesis without removing the well-fixed distal stem.

INTENDED USE

The Global UNITE Shoulder System humeral stems, suture collars, epiphyseal components and humeral heads are intended for cemented or uncemented total shoulder or hemi-shoulder replacement in treatment of the following:

1. A severely painful and/or disabled joint resulting from osteoarthritis, traumatic arthritis or rheumatoid arthritis
2. 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 methods of treatment are unsatisfactory
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When well-fixed, the Global Unite humeral stems, in conjunction with existing Delta Xtend epiphyseal components, are also indicated for conversion to a reverse, in treatment of a grossly deficient rotator cuff joint with severe arthropathy or a previously failed joint replacement with a grossly deficient rotator cuff joint. The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary. The Delta Xtend metaglene is HA-coated and is intended for uncemented use with the addition of screws for fixation. The Delta Xtend epiphyseal components are HA-coated and are intended for uncemented use.

**COMPARISON TO
PREDICATE DEVICE**

Like the predicate device, the subject Global UNITE Shoulder System employs a fluted distal stem, with an epiphysis that features a medial face with a hole for cerclage, as well as anterior/posterior-lateral fins with suture holes to provide a fixation point for tissue reattachment. The subject device features a modular design where the distal stem mates with an epiphyseal body via a pin/hole relationship, along with an anti-rotation tab/slot, and locked together using a captured screw. The stems and epiphyses of both devices are manufactured from medical-grade titanium alloy (Ti-6Al-4V) and both are proximally porous-coated with commercially pure titanium.

The Global UNITE humeral heads are also similar to the predicate Global Advantage humeral heads in that both are fitted with a fixed taper (the predicate has the female taper end on the stem side, whereas the subject has the opposite), are semi-spherical in design, and are manufactured from cobalt-chrome-molybdenum alloy.

Indications and intended use for both subject and predicate devices are the same.

The subject anatomic epiphyseal devices differ from the predicate in that they are modular in design and offer multiple neck shaft angles (128°, 135°, and 142°), whereas the predicate device has an integrated stem-epiphysis design with a fixed 135° neck shaft angle.

Based on similarities in intended use, indications for use, materials, and design, DePuy believes the subject Global UNITE Shoulder System is substantially equivalent to the previously cleared DePuy Global Advantage Shoulder System, cleared in K992065 and K011047.

PERFORMANCE DATA

The following tests were performed (per FDA's *Guidance for Industry and FDA Staff – Class II Special Controls Guidance: Shoulder Joint Metal/Polymer/Metal Nonconstrained or Semi-Constrained Porous-Coated Uncemented Prosthesis*) on the Global UNITE Shoulder System to demonstrate substantial equivalence of safety and efficacy with the predicate device:

- Epiphysis Comparison
- Head Comparison
- Screw Comparison
- Test Rationale
- Fretting and Corrosion
- Torque Test to Failure for Screw Fastener
- Human Torque Test for Screw Fastener
- Fatigue Test for Complete Implant with Lower Torque
- Cadaver Test Report
- Implant Insertion Test

Clinical data was not required for this device.