



JAN 14 1999

K98454/

Summary of Safety and Effectiveness

NAME OF SPONSOR: DePuy Orthopaedics, Inc.
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TRADE NAME: Global™ Shoulder

- Global™ Fx Humeral Stem
- Global™ Advantage® Humeral Head

COMMON NAME: Shoulder prosthesis, humeral stem & head components

CLASSIFICATION: When used as a hemi-shoulder, it is a **Class II** device per 21 CFR §888.3690
When used as a total shoulder, it is a **Class III** device per 21 CFR §888.3660

DEVICE PRODUCT CODE: 87 HSD Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented (Class II)
87 KWS Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented (Class III)

SUBSTANTIALLY EQUIVALENT DEVICE: Global Shoulder: K911686, K914695

DEVICE DESCRIPTION:

The Global Shoulder components, which are the subjects of this submission, consist of a humeral body (stem) and a humeral head. Like the predicate devices, the components are modular in that they employ a morse-type taper lock system, the modular head having the male taper and the body with the female taper. Both components (head and body) will be made from Co-Cr-Mo alloy.

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Summary of Safety and Effectiveness (Continued)

The subject Global *humeral stem* is similar to the current Global humeral stem in that there are four proximal fins, a proximal collar, and a fluted distal stem. The fins are perforated to accommodate the sutures necessary to reconstruct the proximal humerus.

The Global *humeral head* is similar to the current Global head in that it is fitted with an identical locking taper, is semi-spherical in design, and it has similar head sizes and heights. The size range will allow options for joint tensioning and restoration of normal joint biomechanics.

Modifications and Reason: Although the currently marketed design already includes the indication for use in fracture cases, the need for a smaller proximal humeral stem has been identified for those patients with smaller metaphyses and for use in fracture cases when the predicate Global humeral component is too large for the particular patient. DePuy believes the subject humeral components, containing the following described modifications, fill this need.

- The proximal humeral body has been reduced in the A/P and M/L dimensions to ease repositioning of the fractured humeral tuberosities.
- The lateral fin has a reduced profile to prevent contact with the biceps tendon and to avoid tilting the prosthesis in a varus orientation.
- The medial fin has a suture hole added for passing of sutures to reposition fractured tuberosities.
- The lateral fin has one centrally located suture hole versus the three suture holes in the current design.
- The collar diameter has been reduced and contains a flat profile to mate with humeral heads.
- The humeral head has been modified to contain a recess in the undersurface in order to mate with the collar of the humeral stem component. The collar/head design reduces collar/head gap and increases the effective articular surface area.

INTENDED USE:

The subject humeral stem and humeral head are intended for use in total or hemiarthroplasty. When used for total shoulder arthroplasty, the subject components are designed to be used with the existing Global cemented glenoid components cleared in K905786 & K914000. The humeral stem is intended to be used with bone cement or in press-fit applications (cementless).

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Summary of Safety and Effectiveness (Continued)

INDICATIONS FOR USE:

Total or hemi-shoulder replacement is indicated for:

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.

Only the titanium alloy humeral stem components and the cobalt-chrome alloy humeral stem components, which are marketed under the **Global Shoulder** name, are intended for press-fit or cemented fixation. The glenoid components are for cemented use only.

CAUTION:

The cobalt-chrome alloy humeral components, which are marketed under the HRP Shoulder name and all glenoid components are for CEMENTED USE ONLY.

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Summary of Safety and Effectiveness (Continued)

BASIS OF SUBSTANTIAL EQUIVALENCE:

The fundamental scientific technology of the humeral stem and head has not changed from the FDA cleared (K911686) Global Shoulder humeral components. The intended use and indications for use of the subject Global humeral body and head, as described in its labeling has not changed from the FDA cleared (K911686) Global Shoulder devices. The addition of the Global Fx Stem to the Global Shoulder line does not require an application for a new indication because the fracture indication already exists for the currently marketed design. Like the predicate devices in K911686, the humeral head will be manufactured from cobalt chrome alloy. The humeral stem will be manufactured from F-75 cobalt chrome alloy, identical to the humeral component cleared in K914695. With the exception of the minor design modifications previously described, the subject humeral stem and humeral head are identical to the Global Shoulder devices cleared in K911686 and K914695.

Based on conformance with the design control procedures requirements as specified in 21 CFR 820.30, similarities of design, commonly used materials, sterilization processes, indications for use, and intended use, DePuy believes that the subject humeral stem and humeral head components are substantially equivalent to the FDA cleared (K911686 and K914695) Global Shoulder components.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 14 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arlene C. Saull, RAC
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K984541
Global™ Fx Humeral Stem, Global™ Advantage® Humeral Head
Regulatory Class: III
Product Codes: KWT and HSD
Dated: December 18, 1998
Received: December 21, 1998

Dear Ms. Saull:

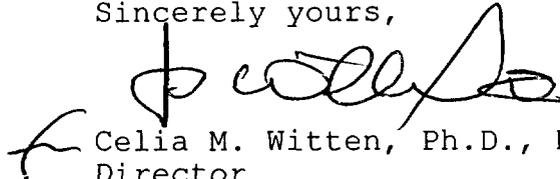
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



510(k) Number (if known) K984541

Device Name: Global™ Shoulder

Indications for Use:

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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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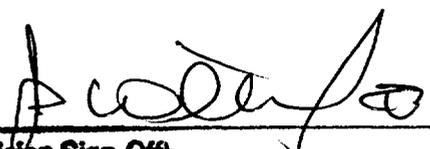
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CAUTION:
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HRP Shoulder name and all glenoid components are for
CEMENTED USE ONLY.

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K984541

Prescription Use X OR Over-The-Counter Use _____
 (Per 21 CFR 801.109)

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