

JUL 12 1999

K992065

Summary of Safety and Effectiveness

NAME OF SPONSOR:

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
Est. Reg. No. 1818910

510(k) CONTACT:

Janet G. Johnson, RAC
Sr. Regulatory Associate
Phone: (219) 372-7176
FAX: (219) 267-7098

TRADE NAME:

Global™ Advantage Shoulder
• Global™ Advantage™ Humeral Stem
• Global™ Advantage™ Eccentric Head

COMMON NAME:

Shoulder prosthesis, humeral stem

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, K974044, K984541

DEVICE DESCRIPTION:

The Global Advantage Shoulder consists of a humeral 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. The humeral stem is manufactured titanium alloy (Ti-6Al-4V), while the humeral head is manufactured from cobalt chromium molybdenum alloy.

The Global Advantage *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 with suture holes to accommodate the sutures necessary to reconstruct the proximal humerus.

The Global Advantage *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 is also available in an offset eccentric head.

Summary of Safety and Effectiveness (Continued)

INTENDED USE:

The Global Advantage Shoulder, humeral stem and humeral head, are intended for use in total or hemi-arthroplasty. 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).

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 either the **Global Shoulder** or **Global Advantage 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.

Summary of Safety and Effectiveness (Continued)

SUBSTANTIAL EQUIVALENCE:

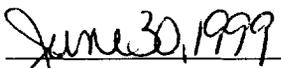
The fundamental scientific technologies of the Global Advantage humeral stem and head have not changed from the FDA cleared (K911686, K974044 and K984541) Global Shoulder humeral stem and head. The intended use and indications for use of the Global Advantage humeral stem and humeral head have not changed from the FDA cleared (K911686) Global Shoulder, Global Eccentric Humeral Head (K974044) and Global Fx (K984541). The humeral stem is manufactured titanium alloy (Ti-6AL-4V), identical to the humeral component cleared in K911686. With the exception of minor design modifications, the Global Advantage humeral stem and humeral head are identical to the Global Shoulder devices cleared in K911686, K974044 and K984541.

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 Global Advantage humeral stem and head are substantially equivalent to the FDA cleared (K911686 K974044 and K984541) Global Shoulder, Global Eccentric humeral head and Global Fx components.

Premarket Notification**Class III Summary and Certification****Global Advantage Total Shoulder****CERTIFICATION:**

I certify, in my capacity as Senior Regulatory Associate, of DePuy Orthopaedics, Inc. that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for total shoulder prostheses. I further certify that I am aware of the types of problems to which total shoulder prostheses are susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems about total shoulder prostheses is complete and accurate.


 Jane G. Johnson, RAC
 Senior Regulatory Associate
 DePuy Orthopaedics, Inc.


 Date

CLASS III SUMMARY:

The most significant complication of total shoulder arthroplasty is currently loosening of the glenoid component. Revision surgery generally follows. Loosening rates for shoulder arthroplasty range from 0% to 11%. The Global Total Shoulder addresses the issue of glenoid loosening in 3 ways:

- 1) Most total shoulder designs rely on hand burring or sculpting to prepare the face of the glenoid bone to accept the prosthesis. This procedure is inaccurate and allows the glenoid prosthesis to seat only on the high points of the bone. With point contact, normal glenohumeral loading tends to rock loose the anchoring fin of the glenoid component. The Global Shoulder system features a glenoid reamer which machines the glenoid to the same radius as the back side of the glenoid prosthesis. These two congruent mating surfaces provide for optimal stress transfer through the range of glenohumeral motion. Loads are transferred through the prosthetic glenoid articular surface to the bone, thereby preventing high stresses in the anchoring fins or pegs.
- 2) Due to the difference in elastic properties between the metal backing and the UHMWPe articular surface, and insufficient locking mechanisms two-piece glenoid components have a tendency to separate. The UHMWPe flexes more than the metal backing which causes the locking mechanism between the two components to fail. The Global Shoulder glenoid component is of a single piece UHMWPe construction, therefore, the possibility of component separation is eliminated.
- 3) The Global Shoulder glenoid is available in two design variations, pegged and finned. The pegged glenoid component has five fixation pegs including one anterior and one posterior peg. These anterior-posterior pegs reduce the rocking type of motion that can cause glenoid loosening. The finned glenoid component has a traditional tapered fixation fin. The finned component could be used in revision cases where a trough already exists in the glenoid bone or in cases of poor glenoid bone stock.

Premarket Notification

Class III Summary and Certification (continued)

Other types of safety and effectiveness problems associated with total shoulder arthroplasty are also associated with other total joint replacements. These include:

- Change in position of the prosthesis.
- Early or late infection.
- Cardiovascular disorders (including venous thrombosis, pulmonary embolism, and myocardial infarction which may be related to the use of bone cement).
- Hematoma and delayed wound healing.
- Pneumonia and atelectasis.
- Subluxation or dislocation of the implant due to size selection, positioning of components and/or muscle and fibrous tissue laxity.
- Failure to relieve pain.
- Failure to restore range of motion.

In order to reduce the chance of complications with a total shoulder arthroplasty, the following conditions (which tend to impose severe loading on the affected extremity and may tend to adversely affect safety or effectiveness of a total shoulder arthroplasty) should be reduced or eliminated:

- Heavy labor.
- Active sports participation.
- Likelihood of falls.
- Alcohol or drug addiction.
- Obesity.

The following conditions tend to adversely affect the stability (safety or effectiveness) of the implants:

- Marked osteoporosis with poor bone stock and danger of impaired abutment of implants.
- Systemic and metabolic disorders leading to progressive deterioration of solid bone support for the implant (e.g. cortisone therapies, immunosuppressive therapies).
- History of general infectious disease (e.g. erysipelas) or local infectious disease.
- Severe deformities leading to impaired anchorage or improper positioning of the implant.
- Tumors of the supporting bone structure.
- Allergic reactions to the implant materials.
- Tissue reactions to corrosion or wear products.

Attached is a bibliography of the materials upon which this summary is based.

BIBLIOGRAPHY

1. Neer, C.S., Watson, K.C., Stanton, F.J.: Recent Experience in Total Shoulder Replacement. *The Journal of Bone and Joint Surgery*, 64A(3):319-336, 1982.
2. Faludi, D.D., Weiland, A.J.: Cementless Total Shoulder Arthroplasty: Preliminary Experience with Thirteen Cases. *Orthopedics*, 6(4):431-437, 1983.
3. Cofield, R.H.: Total Shoulder Arthroplasty: Associated Disease of the Rotator Cuff, Results and Complications. *Surgery of the Shoulder*, 229-233.
4. Boyd, A.D., Thomas, W.H., Scott, R.D., Sledge, C.B., Thornhill, T.S.: Total Shoulder Arthroplasty Versus Hemiarthroplasty. *The Journal of Arthroplasty*, 5(4):329-336, 1990.
5. Gristina, A.G., Romano, R.L., Kammire, G.C., Webb, L.X.: Total Shoulder Replacement. *Management of Shoulder Problems*, 445-453.
6. Lettin, A.W., Copeland, S.A., Scales, J.T.: The Stanmore Total Shoulder Replacement. *The Journal of Bone and Joint Surgery*, 64B(1):47-51, 1982.
7. Hawkins, R.J., Bell, R.H., Jallay, B.: Total Shoulder Arthroplasty. *Clinical Orthopedics and Related Research*, 242:188-194, 1989.
8. Barrett, W.P., Franklin, J.L., Jackins, S.E., Wyss, C.R., Matsen, F.A.: Total Shoulder Arthroplasty. *The Journal of Bone and Joint Surgery*, 69A(6):865-872, 1987.
9. Neer, C.S.: Unconstrained Shoulder Arthroplasty. *Surgery of the Shoulder*, 240-245.
10. Wilde, A.H., Borden, L.S., Brems, J.J.: Experience with the Neer Total Shoulder Replacement. *Surgery of the Shoulder*, 224-228.
11. Orthopedic Surgical Manufacturers Association (OSMA): Petition for Reclassification of Shoulder Joint Metal/Polymer Non-constrained and Semi-constrained Cemented, Press Fit Hemi and Total Shoulder Prostheses. Submitted to FDA October 25, 1989.
12. DePuy Package Insert for the Total Shoulder or Hemi-Shoulder Prosthesis for Cement Fixation, No. 0902-00-457, Issued 1-95.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 1999

Janet G. Johnson, RAC
Senior Regulatory Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

Re: K992065
Trade Name: Global Advantage Shoulder: Humeral Stem and Eccentric Head
Regulatory Class: III
Product Code: KWS and HSD
Dated: June 17, 1999
Received: June 18, 1999

Dear Ms. Johnson:

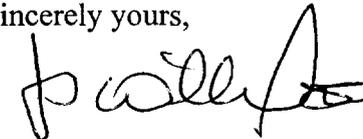
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



f 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): _____

Device Name: Global™ Advantage Shoulder

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).

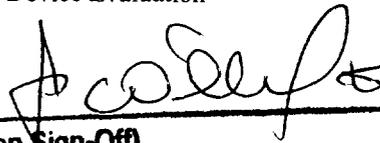
Hemi-shoulder replacement is also indicated for:

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 either the **Global Shoulder** or **Global Advantage 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.**

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number 12992065

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