

K981487

JUL 13 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM: DePuy, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

FIRM CONTACT: Sally Foust
Regulatory Submissions Associate
(219) 372-7455; FAX (219) 267-7098
E-Mail: Sally_Foust@ccgate.depuy.com

TRADE NAME: DePuy Global Shoulder Glenoid

COMMON NAME: Shoulder Prosthesis

DEVICE PRODUCT CODE: 87 KWS – prosthesis, shoulder, semi-constrained
metal/polymer, cemented

SUBSTANTIALLY EQUIVALENT DEVICES:

- DePuy Global Total Shoulder System
- Global Total Shoulder with DuPont Enhanced UHMWPe

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Global Shoulder Glenoid is intended for cemented use as the glenoid component in total shoulder arthroplasty, completed using humeral components of the DePuy Global Total Shoulder System. The DePuy Global Shoulder Glenoid is manufactured in six sizes from Ultra High Molecular Weight Polyethylene (UHMWPe). The component's articular (lateral) surface is concave and is designed to articulate with the head of an existing, commercially available Global Shoulder humeral prosthesis. The fixation (medial) surface is convex and is designed with four pegs, one centrally located peg and three peripheral pegs placed in a triangular configuration. The centrally located peg is fitted with radially extending fins spaced longitudinally along the center which provide interdigitation with cement. The three peripheral pegs provide resistance to rocking and rotational motion caused by translation of the prosthetic humeral head.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The DePuy Global Shoulder Glenoid component described in this premarket notification is identical to the currently marketed cemented DePuy Global Shoulder Pegged and Keeled Glenoid components in terms of material (UHMWPe), articular and fixation surface geometries, and use as the cemented glenoid component in total shoulder arthroplasty, completed using humeral components of the DePuy Global Total Shoulder System.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Sally Foust
Regulatory Submissions Associate
DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopedic Drive
Warsaw, Indiana 46581-0988

Re: K981487
Trade Name: DePuy Global Shoulder Glenoid
Regulatory Class: III
Product Code: KWS
Dated: April 24, 1998
Received: April 27, 1998

Dear Ms. Foust:

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). This decision is based on this device being equivalent only to similar devices labeled and intended to be fixed with acrylic "bone cement." You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. This device may not be labeled or promoted for non-cemented use.
2. All labeling for this device, including package label and labeling included within the package, must prominently state that the device is intended for cemented use only.
3. Any non-cemented fixation of this device is considered investigational and may only be investigated as a significant risk device in accordance with the investigational device exemption (IDE) regulation under 21 CFR, Part 812. All users of the device for non-cemented fixation must receive approval from their respective institutional review boards (IRBs) and the Food and Drug Administration (FDA) to conduct the investigation.

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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.

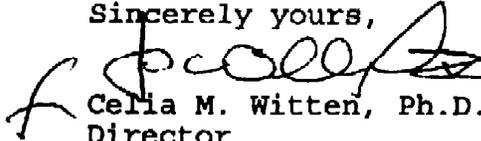
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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

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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) K9B1487

Device Name DePuy Global Shoulder Glenoid

The DePuy Global Shoulder Glenoid is intended for use as a cemented glenoid component in total shoulder arthroplasty completed using humeral components of the DePuy Global Total Shoulder System.

The subject device *DePuy Global Shoulder Glenoid* is part of the *Global Total Shoulder System*.

Indications for Use:

The humeral components of the Global Total Shoulder System are intended for cemented or cementless use as a total or hemi-shoulder replacement which is indicated for: ←

1. A severely painful and/or a severely disabled joint resulting from osteoarthritis, traumatic arthritis, or rheumatoid arthritis;
2. Fracture-dislocations of the proximal humerus where the articular surfaces are severely comminuted, separated from blood supply or where experience shows more conventional methods of treatment are unsatisfactory;
3. Other difficult clinical management problems where arthrodesis or resection are not acceptable (i.e. revision of a failed primary component).

The glenoid components of the Global Total Shoulder System are intended for cemented use only for the above indications.

Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures of long duration: [Signature]
 2. Avascular necrosis of the humeral head. [Signature]
- (Division Sign Off)
Division of General Restorative Devices
510(k) Number 12581487

Concurrence of CDRH, Office of Device Evaluation

Prescription Use Yes OR Over-The-Counter Use No
(Per 21 CFR 801.109)

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