510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

EXHIBIT 2

K974044

JAN 22 1998

NAME OF FIRM:

DePuy, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

510(K) CONTACT:

Arlene C. Saull, RAC
Sr. Submissions Associate
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, IN 46581-0988

TRADE NAME:

Global™ Total Shoulder Eccentric Humeral Head

COMMON NAME:

Total Shoulder Prosthesis, or Hemi-Shoulder Prosthesis

CLASSIFICATION:

Class III, when used as a total shoulder per 21 CFR, 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis.

Class II, when used as a hemi-shoulder per 21 CFR, 888.3690. Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.

DEVICE PRODUCT CODE:

87 KWS: Prosthesis, Shoulder, Semi-Constrained Metal/Polymer, Cemented (Class III)

87 HSD Prosthesis, Hemi-Shoulder, Humeral, Metallic Uncemented (Class II)

SUBSTANTIALLY EQUIVALENT DEVICES:

DePuy Global™ Total Shoulder
DePuy Global™ Total Shoulder, Humeral Component, for Cemented or Uncemented Use

DEVICE DESCRIPTION AND INTENDED USE:

The DePuy Global Total Shoulder Eccentric Humeral Head will be available in a variety of sizes which are designed with offset male tapers to be used with the currently marketed DePuy Global Total Shoulder Humeral Bodies and Glenoid Components. The male taper on the Global Total Shoulder Eccentric Humeral Head is shifted 4.0mm off the head center. This offset permits the head to be "dialed" to cover the cut surface of the proximal humerus. This allows placement of the head in a more anatomically aligned position.

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

Ex. 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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 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;

2. Avascular necrosis of the humeral head.

BASIS OF SUBSTANTIAL EQUIVALENCE:
The subject Global Total Shoulder *Eccentric* Humeral Heads are identical in design to the predicate Global Total Shoulder *(standard)* Humeral Head with the exception that the male taper is offset 4.0mm.

The subject Global Total Shoulder Eccentric Humeral Heads are designed to be used with the same humeral bodies and glenoid components as the predicate standard humeral heads. The geometry of the articular surface of the subject eccentric humeral head is identical to that of the predicate standard concentric humeral head, thus the contact area will remain the same.

The subject Global Total Shoulder Eccentric Humeral Head is similar in material, sizes, intended use, and design to the predicate Global Total Shoulder (standard) Humeral Heads, with the exception of the eccentricity (offset) of the male taper of the subject device versus the concentricity of the male taper of the predicate device.

The indications for use are the same for both and they replace the same anatomic structures. Also, the Co-Cr-Mo alloy material of the subject eccentric humeral head is the same as that used for the predicate device.

Based on the information provided in this premarket notification DePuy considers the Global Total Shoulder Eccentric Humeral Head to be substantially equivalent to the predicate Global Total Shoulder (standard) Humeral Head currently marketed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 22 1998

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

Re: K974044
Global™ Total Shoulder Eccentric Humeral Head
Regulatory Class: III
Product Codes: KWS and HSD
Dated: October 23, 1997
Received: October 24, 1997

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). This decision is based on the humeral component being used as a cemented or uncemented humeral hemi-shoulder, or as the cemented or uncemented humeral component of a total shoulder system which has a cemented glenoid component. You may, therefore, market your device subject to the general controls provisions of the Act and the following limitations:

1. The glenoid component of the Global Total Shoulder 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 glenoid component is intended for cemented use only.

3. Any non-cemented fixation of the glenoid component 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 glenoid component 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.

The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, 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 immediately. An FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and 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,

for 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

EXHIBIT 1

INDICATIONS

510(k) Number (if known) ____________________

Device Name Global™ Total Shoulder

The subject device Global Shoulder Eccentric Humeral Head is part of the Global Total Shoulder System.

Indications for Use:

The humeral components of the Global Total Shoulder 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).

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Hemi-shoulder replacement is also indicated for:

1. Ununited humeral head fractures of long duration;

2. Avascular necrosis of the humeral head.

Concurrence of CDRH, Office of Device Evaluation:

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974044

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