AUG - 1

510(k) SUMMARY

K971715

April 29, 1997

In accordance with the Food and Drug Administration Interim Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21CFR 807, this is to serve as a 510(k) Summary for the Sulzer Orthopedics Inc. Select® Shoulder Offset Humeral Heads.

Submitter: Sulzer Orthopedics Inc.
9900 Spectrum Drive
Austin, TX 78717
(512) 432-9900

Contact Person: Jacquelyn Hughes
Manager, Regulatory Affairs

Classification Name: No formal classification has been established for humeral head components.

Common/Usual Name: Humeral Head Components

Trade/Proprietary: Select® Shoulder Offset Humeral Heads

Product Description/Substantial Equivalence:

The Select Shoulder Offset Humeral Heads are metallic components manufactured from cobalt chrome alloy (CoCrMo). The heads, once impacted onto one of the Select Shoulder humeral stems, are designed to articulate with the normal human glenoid or with a replacement all-poly glenoid component. The humeral heads feature a female taper which allows for attachment to the male taper of the Sulzer Orthopedics Select Shoulder Humeral Stems. The articulating surface of the head is polished. The underside of the head, with the exception of the taper attachment feature, may be either polished or grit blasted. Similar to the face of a clock, the underside of the head is numbered from 1-12, giving the surgeon the ability to reference and select the position of the head relative to the glenoid. The location of the female taper is offset from center, thus permitting ease of insertion into the joint, allowing closer replication of the normal head anatomy permitting accurate anatomic soft tissue balancing, and providing greater contact with the glenoid when the humerus is in a normal resting position. The heads are available in a variety of heights and diameters. The humeral heads are designed for use with Sulzer Orthopedics Humeral Stems and/or glenoid components which come in a variety of sizes for increased stability of the glenohumeral joint.

Testing indicated that the pulloff strengths for the Select Shoulder Offset Humeral Heads were comparable to currently marketed devices. Contact area testing indicated that the offset heads provide adequate contact area at various levels of abduction.

The Select Shoulder CoCr Humeral Heads are similar to those of the Tornier Aequalis Shoulder System, the Depuy Global Total Shoulder System, the Biomet Bio-Modular Total Shoulder, the Zimmer Fenlin Total Shoulder, the Kirschner Modular Shoulder System, the 3M/Orthomet Modular Neer II Shoulder System, and the Encore Foundation Shoulder System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mitchell A. Dhority, RAC
Senior Regulatory Affairs Specialist
SulzerMedica
Sulzer Orthopedics, Inc.
9900 Spectrum Drive
Austin, Texas 78717

AUG - 7 1997

Re: K971715
Trade Name: Select Shoulder Offset Humeral Heads
Regulatory Class: III
Product Codes: KWS, KWT, and HSD
Dated: May 7, 1997
Received: May 9, 1997

Dear Mr. Dhority:

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.

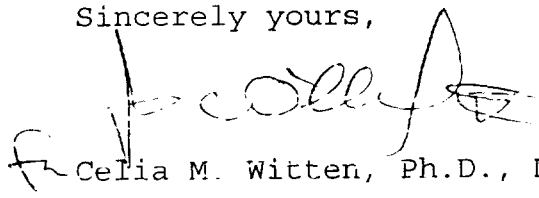
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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): K971715

Device Name: Select Shoulder Offset Humeral Heads

Indications for Use:

The Select Shoulder Offset Humeral Heads, when used with one of the Select Shoulder Humeral Stems and Glenoid Components (if applicable), are intended for use in treatment of the following:

1. Patient conditions, including but not limited to, noninflammatory degenerative joint disease (NIDJD), e.g., osteoarthritis or post-traumatic arthritis, and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.

2. Complex acute fractures, fracture-dislocations of the humeral head, malunion or non-union of a small osteoporotic head fragment, chronic, recurrent or acute dislocation with loss of humeral head cartilage, or large impression fractures.

3. Those patients with failed previous surgery where pain, deformity, or dysfunction persists.

4. Failed previous surgery, including joint reconstruction, internal fixation, nonunion of the humeral neck, arthrodesis or hemiarthroplasty.

5. Cuff tear arthropathy.

6. Avascular necrosis or osteonecrosis of the humeral head.

7. Tumor resection.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971715

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

(Optional Format 1-2-96)