K970567

510(k) SUMMARY

February 13, 1997

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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 Curved-back Pegged All-Poly Glenoids.

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Contact Person:	Jacquelyn Hughes Regulatory Affairs Manager
Classification Name:	21 CFR Part 888.3650 - Shoulder joint metal/polymer non-constrained cemented prosthesis
Common/Usual Name:	Glenoid prosthesis
Trade/Proprietary:	Select® Shoulder Curved Back Pegged All-Poly Glenoids

Product Description/Substantial Equivalence:

The Curved-back Pegged All-Poly Glenoid is a one piece, polyethylene (ASTM F648) design intended to reproduce the function of the natural glenoid. The design is such that the component may be used in either the right or left shoulder. The implant is cemented into the subchondral bone of the glenoid cavity providing a cement mantle of approximately 1-2 mm.

This design features a curved articulating surface. The underside of the component has two grooved pegs bounded by two dovetail cement grooves which provide translational and rotational stability to the implant as well as to enhance cement fixation. The grooves in the pegs also allow the surgeon to intraoperatively trim the length in the event that the glenoid vault is shallow and prevents the full length from being seated. Titanium (ASTM F136) x-ray marker pins are incorporated in the superior and inferior aspects of the component to assist in postoperative evaluation. The lateral surface of the glenoid component accommodates the humeral head. The articulating geometry is nonconstrained for greater range of motion and greater translation.

Contact area testing indicates that the Curved-back Pegged All-Poly Glenoids offer adequate contact area at various levels of abduction.

The designs are substantially equivalent to the Select Shoulder Pegged All-Poly Glenoids and Keeled All-Poly Glenoids as well as those glenoids used in the Orthomet/3M Modular Neer II Shoulder System, the Zimmer Fenlin Total Shoulder, the Smith & Nephew Richards Cofield

Shoulder, the Kirschner/Biomet Modular Shoulder, the Biomet Bio-Modular Total Shoulder, and the Depuy Global Total Shoulder System.

The Select Shoulder Curved-back Pegged All-Poly Glenoids, when used with one of the Select Shoulder Humeral Stems and Humeral Heads, are intended only for use with bone cement in cases of total shoulder arthroplasty for 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.