

510(k) SUMMARY

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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 Intermedics Orthopedics, Inc. Select® Shoulder All-Poly Glenoids.

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Classification Name: 21 CFR Part 888.3650 - Shoulder joint metal/polymer non-constrained cemented prosthesis

Common/Usual Name: Glenoid prosthesis

Trade/Proprietary: Select® Shoulder Pegged All-Poly Glenoids

Product Description/Substantial Equivalence:

The Pegged All-Poly (ASTM F648) Glenoid is a one piece design intended to reproduce the function of the natural glenoid. The design of this glenoid component allows use in 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.

The Pegged All-Poly Glenoid Component features a flat back, two grooved pegs and a circumferential dovetail cement groove on the medial surface to provide translational and rotational stability to the implant as well as to enhance cement fixation. The peg grooves allows for intraoperative trimming in the event of shallow glenoid anatomy. The concave lateral surface of the glenoid implant accommodates the humeral head. The geometry of the component is non-constrained. Titanium pins in the inferior and superior aspects of the component assist in postoperative evaluation.

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

The designs are substantially equivalent to the 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.

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