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510(k) SUMMARY

K962238

June 7, 1996

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.

Submitter:	Intermedics Orthopedics, Inc. 9900 Spectrum Drive Austin, TX 78717 (512) 432-9900
Contact Person:	Jacquelyn Hughes Regulatory Affairs Manager
Classification Name:	21 CFR Part 888.3650 - Shoulder joint metal/polymer non-constrained cemented prosthesis 21 CFR Part 888.3660 - Shoulder joint metal/polymer semi-constrained cemented prosthesis
Common/Usual Name:	Glenoid prosthesis
Trade/Proprietary:	Select® Shoulder Keeled All-Poly Glenoids

Product Description/Substantial Equivalence:

The Keeled All-Poly (ASTM F648) Glenoids are one piece designs intended to reproduce the function of the natural glenoid. The design of these glenoid components 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 Keeled All-Poly Glenoid Component features curved back with a keel on the medial surface to provide translational and rotational stability to the implant. A circumferential groove around the middle of the keel allows for intraoperative trimming in the event of shallow glenoid anatomy. The concave lateral surface of the glenoid implant accommodates the humeral head. Dovetail cement grooves on either side of the keel provide enhanced cement fixation. Non-constrained and congruent designs will be available to address varying size and stability requirements. Titanium x-ray marker pins have been attached to the inferior and superior aspects to assist in postoperative evaluation.

Contact area testing indicates 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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