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510(k) SUMMARY

February 5, 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. Apollo Total Knee System Single Lug Patella.

Submitter: Intermedics Orthopedics, Inc.
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Contact Person: Jacquelyn Hughes
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Classification Name: Knee joint femorotibial metal/polymer semi-constrained cemented prothesis, 21 CFR 888.3530.

Common/Usual Name: Single Lug All-Polyethylene Patella

Trade/Proprietary: Apollo Total Knee System Single Lug Patella

Product Description/Substantial Equivalence:

The Apollo Knee System Single Lug Patella is designed to articulate with the various tibial and femoral components of the Apollo Total Knee System. The Single Lug Patella is a one piece component manufactured from ultra-high molecular weight polyethylene (UHMWPE, ASTM F648). The design incorporates a large, round, centrally placed, single lug on the back of the component for fixation. A concentric cement groove is incorporated into the stem of the single lug to aid in cement adhesion. A discontinuous dovetail cement groove has also been incorporated into the flat surface on the back of the patella to aid in achieving a bone cement "macro-lock" and to assist in rotational stability of the implant. The component will be available in a 28mm round design as well as 29mmX32mm, 32mmX35mm, and 35mmX38mm elliptically shaped design.

The Apollo Total Knee System Single Lug Patella is also similar to the Smith & Nephew Richards Genesis All-Poly Patella, the Zimmer Insall-Burstein II All-Poly Patella, the Johnson & Johnson PFC All-Poly Patella, the Biomet Maxim All-Poly Patella, the Biomet AGC All-Poly Patella, and the Orthomet Axiom All-Poly Patella.