

JUL 9 1996

K961589
510(k) SUMMARY

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. APR® Fully Textured Hip Stem.

Submitter: Intermedics Orthopedics, Inc.
9900 Spectrum Drive
Austin, TX 78717
(512) 432-9687

Date: April 23, 1996

Contact Person: Jacquelyn Hughes
Manager, Regulatory Affairs

Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21CFR 888.3353

Common/Usual Name: Femoral Component

Trade/Proprietary: APR® Fully Textured Hip Stem

Product Description/Substantial Equivalence:

The APR® Fully Textured Hip Stem is intended for prosthetic replacement of the proximal portion of the femur in a hip replacement. This device is a nonporous, anatomic femoral component that comes in a variety of sizes in both left and right configurations. This stem is manufactured from wrought Ti-6Al-4V alloy (ASTM F 136) and features surface texturing along the full length of the stem (with the exception of the neck area) for enhanced fixation in cemented or press-fit applications. In addition, the APR® Fully Textured Hip Stem:

- incorporates an anterior angulation in the proximal body to match the normal anterior angulation of the natural femur;
- features a double wedge shaped proximal body to maximize filling of the proximal femur;
- has a 12/14 Morse taper making it compatible with modular femoral heads;
- has a distal stem with a circular cross section allowing for ease in canal preparation and prosthesis insertion; and;
- incorporates a cylindrical hole in the distal stem of the larger sizes to increase distal stem flexibility.

The APR® Fully Textured Hip Stem is substantially equivalent to the Bi-Metric Primary Interlok Hip Stem (Biomet, Inc.) and the Alloclassic Zweymüller Cementless Stem (Sulzer Orthopedics, AG).

000221