

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® Oversized Hip Stem.

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

K961921

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Contact Person: Jacquelyn Hughes
Manager, Regulatory Affairs

Classification Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis, 21 CFR 888.3358
Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis, 21CFR 888.3353

Common/Usual Name: Femoral Component

Trade/Proprietary: APR® Oversized Hip Stem

Product Description/Substantial Equivalence:

The APR Oversized Hip Stem is an anatomic femoral component that is intended for prosthetic replacement of the proximal portion of the femur in a hip replacement. This device is manufactured from wrought Ti-6Al-4V alloy (ASTM F 136) and is available in both porous and nonporous versions for use in cemented or press-fit applications. The APR Oversized Hip Stem will be offered with the intent of augmenting IOI's anatomic product line by addressing the metaphyseal/diaphyseal mismatch found in a significant portion of the patient population. While the currently marketed APR Hip Stem is a proportional design, the APR Oversized Hip Stem is designed for the Type A endosteal canal in which the diaphysis is disproportionately smaller than the metaphysis. By adding this "proximally upsized," or "oversized," version to the currently marketed product line, the surgeon can obtain good fit and fill of the medullary canal without sacrificing distal cortical bone in those patients which exhibit proximal/distal mismatch. Specific diagnostic indications for use of the APR Oversized Hip Stem include:

- patient conditions of rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, and arthritis secondary to a variety of diseases and anomalies;
- avascular necrosis of the femoral head and/or non-union of femoral neck fractures;
- femoral fractures; and
- fracture dislocation of the hip.

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The strength of the APR Oversized Hip Stem was analyzed using theoretical calculations and fatigue loading conditions and shown to be comparable to other legally marketed devices.

The APR Oversized Hip Stem is substantially equivalent to the OMNIFIT[®] Specialty[™] Femoral Stem (Osteonics Corp.), the PFC[™] Total Hip System (Johnson & Johnson, Inc.), the Ranawat/Burstein[™] Total Hip System (Biomet, Inc.), and the Stability[™] Total Hip System (DePuy, Inc.).