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## 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21CFR 807, this is to serve as a Summary of Safety and Effectiveness for the InterMoore Fracture Hip Stem.

**Submitter:** Intermedics Orthopedics, Inc.  
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**Classification Name:** Hip Joint Femoral (Hemi-Hip) Metallic Cemented or Uncemented Prosthesis, 21CFR 888.3360

**Common/Usual Name:** Hip Stem for Hemi-Arthroplasty or Total Hip Replacement

**Trade/Proprietary Name:** InterMoore Fracture Hip Stem

### PRODUCT DESCRIPTION/SUBSTANTIAL EQUIVALENCE

The InterMoore Fracture Hip Stem is intended for prosthetic replacement of the proximal portion of the femur in hip replacements (i.e., total hip replacement or hemi-arthroplasty). This device will be manufactured from either cast, forged, or wrought Cobalt-Chromium (CoCr) alloy conforming to ASTM Standards F75, F799, and F1537, respectively. This straight stem is offered in a variety of sizes to allow the surgeon to replicate the natural anatomy of the hip joint as closely as possible when performing a femoral replacement. In addition, the InterMoore Fracture Hip Stem:

- has a broad collar which wraps around the anterior, medial, and posterior sides.
- incorporates a stem-neck angle which replicates natural anatomy.
- is available in a fenestrated design for press-fit applications and a solid design for press-fit and cemented applications.
- has a 12/14 Morse-type male taper making it compatible with any Intermedics Orthopedics, Inc. 12/14 metal femoral head (e.g., modular femoral head, unipolar) or bipolar component which utilizes a 12/14 modular femoral head.
- provides lateral offsets ranging from 32 to 49mm.
- incorporates I-beam grooves along the anterior and posterior surfaces to increase rotational stability *in vivo*.
- has a roughened/grit-blasted surface below the collar, to enhance fixation *in vivo*.
- will incorporate a proximal, lateral fin to the fenestrated design. This fin will increase the rotational stability of the implant *in vivo*.

The InterMoore Fracture Hip Stem is substantially equivalent to the Apollo Hip Stem™ offered by Intermedics Orthopedics, Inc., the Modular Austin Moore Hip Stem offered by Zimmer, Inc., the Bio-Moore II Stem offered by Biomet, Inc. and the Hip Fracture Stem offered by Howmedica, Inc.

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