

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

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

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Contact Person: Jacquelyn Hughes
Manager, Regulatory Affairs

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

Common/Usual Name: Total Hip Prosthesis - Femoral Component

Trade/Proprietary Name: Natural-Hip™ System CoCr Revision Stem

Device Description: The Natural-Hip System CoCr Revision Stem is fabricated from either forged or wrought cobalt chromium alloy which conforms to the American Standards for Testing and Materials (ASTM) standards F-799 or F-1537, respectively.

The Natural-Hip System CoCr Revision Stem features a threaded Sulzer 12/14 configured neck trunnion for attachment to IOI's currently marketed femoral heads, including Biolox and Zirconia heads, employing a Sulzer 12/14 configured bore.

The Natural-Hip System CoCr Revision Stem is available in both a collared and collarless design. The proximal one-third of the stem's surface employs normalization steps and is roughened via the process of grit blasting. The normalization steps and grit blasted surface enhance cement compression and bonding for optimal fixation of the hip stem in the femoral canal. The proximal surface of the Natural-Hip System CoCr Revision Stem also employs polymethylmethacrylate (PMMA) cement centralizers to provide even cement mantle when the stem is implanted in the femur.

The distal portion of the Natural-Hip System CoCr Revision Stem is bowed to mimic the anatomy of the femur. The Natural-Hip System CoCr Revision Stem employs a hole in the distal portion

of the stem to allow the use of a PMMA centralizer for correct distal alignment.

The Natural-Hip System CoCr Revision Stem is intended to be used in conjunction with the following Intermedics Orthopedics, Inc. (IOI) devices that have been cleared for marketing by the FDA:

- IOI metallic femoral bearing heads [510(k)s K905781 and K913060],
- IOI Biolox Bearing Heads [510(k)s K923734 and K942330]
- Zirconia Bearing Heads [510(k) K944209],
- IOI bipolar components [510(k)s K833404 and K873815],
- IOI unipolar components [510(k)s K833403 and K934159],
- IOI acetabular components [510(k)s K850793, K920955, K933203, K942406, K941617, K955033 and K955739].

Diagnostic Indications

The Natural-Hip System CoCr Revision Stem is intended to replace the anatomy of the femur in cases of total hip or hemi-hip replacement. The Natural-Hip System CoCr Revision Stem is intended for cemented application only and is intended for single use only. The Natural-Hip System CoCr Revision Stem is intended for use in treatment of the following:

1. Patient conditions of non-inflammatory degenerative joint disease (NIDJD), e.g., avascular necrosis, osteoarthritis and inflammatory joint disease (IJD), e.g., rheumatoid arthritis.
2. Those patients with failed previous surgery where pain, deformity or dysfunction persists.
3. Revision of previously failed arthroplasty.

Predicate Devices:

The features employed by Natural-Hip System CoCr Revision Stem are substantially equivalent to the features employed by the following predicate legally marketed devices:

- Omnifit® Long Stem: Osteonics Corporation [510(k) number unknown to IOI].
- Ultima® Long Stem: Johnson & Johnson Professional Inc. [510(k) K952859].
- PCA® Long Stem: Howmedica Inc. [510(k) number unknown to IOI].
- Matrix Cementra® Revision Femoral Stem: Smith & Nephew Richards [510(k) Number unknown to IOI].