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Summary of Safety and Effectiveness for Natural Hip System Porous Stem

K963266

August 19, 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 Natural Hip System Porous Stem.

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Proprietary name

Natural Hip System Porous Stem

Common Name:

Total Hip Prosthesis - Femoral Component

Classification name:

Hip joint metal/ceramic/polymer semi-constrained porous coated uncemented prosthesis, 21 CFR 888.3358

Predicate Devices:

The features employed by Natural Hip Stem Porous Stem are substantially equivalent to the features employed by the following predicate legally marketed devices:

- Porous Natural Hip Stem: Intermedics Orthopedics, Inc. (510(k) K913060).
- Stability Hip Stem: Depuy Inc. (510(k)s K915787 and K934457).

Device Description:

The Natural Hip System Porous Stem is identical in design geometry as compared to the predicate IOI Porous Natural Hip Stem, except for the reduction in the neck length. This design change was intended to address various patient population in cases of total hip or hemi-hip arthroplasty.

The Natural Hip System Porous Stem employs a Sulzer 12/14 configured neck trunnion for attachment to IOI's femoral heads, including Biolox and Zirconia ceramic heads, featuring a Sulzer 12/14 configured bore.

The Natural Hip System Porous Stem is available in both collared and collarless design. The Natural Hip System with Collar employs Cancellous Structured Titanium (CSTi™) porous coating on the inferior surface of the collar.

The proximal surface of the Natural Hip System Porous Stem employs anterior angulation to match the anatomic angulation of a natural femur. In addition, the proximal surface of the Natural Hip System Porous Stem employs circumferential CSTi™ porous coating

The distal portion of the Natural Hip System Porous Stem employs ribs and flutes on the anterior and posterior sides of the hip stem. In addition, the distal portion of the Natural Hip System Porous Stem employs a flared coronal slot.

The results of the theoretical stress analysis demonstrate that the Natural Hip System Porous Stem can successfully endure a fatigue test regimen of 10 million cycles without compromising the integrity of the hip stem.