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510(k) Premarket Notification
Summary of Safety and Effectiveness
for
Natural Hip System - DRG Hip Stem

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 DRG Hip Stem.

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Proprietary name Natural Hip System - DRG Hip Stem

Common Name: Total Hip Prosthesis - Femoral Component

Classification name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis (21CFR 888.3353).

Predicate Devices: The features employed by the DRG Hip Stem are substantially equivalent to the features employed by the following predicate legally marketed devices:

- Premier Total Hip Stem: Intermedics Orthopaedics Inc. (510(k) #K894051).
- Osteonics ODC Cemented Hip Stem: Osteonics Corporation (510(k) number unknown to IOI).
- Osteonics ODC Hip Stem: Osteonics Corporation (510(k) number unknown to IOI).

- Perfecta IMC Stem: Orthomet Inc. (510(k) number unknown to IOI.

Device Description:

The DRG Hip Stem employs a Sulzer 12/14 configured threaded trunnion for attachment to IOI's femoral bearing heads. The DRG Hip Stem is available with or without a proximal collar. The proximal collar enhances cement pressurization in cases of cemented total hip arthroplasty. The DRG Hip stem employs a widened or expanded proximal geometry for enhanced fit of the stem in the metaphyseal canal of the femur. The widened or expanded proximal geometry of the hip stem is designed to reduce stresses that can potentially cause cement/bone or bone/prosthesis interface breakdown.

Surface enhancement via grit blasting is employed on the entire length of hip stem below the collar. Grit blasted surfaces provide enhanced fixation in both cemented and cementless total hip arthroplasties. In a cemented application, the grit blasted surfaces provide a greater interdigitation with bone cement. In a press-fit or cementless application, the grit blasted surfaces provide an enhanced bone/prosthesis interface.

The distal portion of DRG Hip Stem employs a hole for the attachment of a distal centralizer fabricated from polymethylmethacrylate (PMMA).

Intended Use:

The DRG Hip Stem is intended to replace the anatomy of the femur in cases of total hip replacement. In addition, the DRG Hip Stem, like the predicate IOI and competitive hip stems, is intended for cemented or cementless (press-fit) application in cases of total hip arthroplasty.

The general indications associated with the use of DRG Stem in total hip arthroplasty include:

1. Patient conditions of 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.

Summary of Technological Characteristics:

A side by side tabular comparison of the characteristics of the DRG Hip Stem to those of the currently marketed IOI and competitive devices follows.

Characteristics	Subject Device	Predicate Devices			
	DRG Hip Stem	Premier Total Hip Stem	ODC Fx Hip Stem	ODC Hip Stem	Perfecta IMC Stem
Manufacturer	IOI	IOI	Osteonics	Osteonics	Orthomet
510(k)#	-	K894051	Unknown	Unknown	Unknown
Material	Wrought or Forged CoCr	Titanium alloy	Cast CoCr	Cast CoCr	Forged CoCr alloy
Intended Use	Cemented/ Cementless	Cemented	Cemented	Cemented	Cemented
Proximal wedge shaped design	Yes	Yes	Yes	Yes	Yes
Proximal collar	Available with or without collar	Yes	Yes	Yes	Yes
Surface Enhancement Via Grit Blasting	Entire length below the collar of the hip stem	Proximal third only	Entire length below the collar	Proximal third only	Proximal third only
Distal Canal Centralizer	Yes	Yes	No	Yes	Yes
Neck Lengths	25-41mm	35mm	25-35mm	25-40mm	Unknown
Sizes	5 sizes	7 sizes	5 sizes	7 sizes	6 sizes