

K961727

**510(k) Premarket Notification  
Summary of Safety and Effectiveness  
for  
Calcar Replacement Hip Stem**

**JUL 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 Calcar Replacement Hip Stem.

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**Date:** February 15, 1996

**Proprietary name** Natural Hip System  
Calcar Replacement 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 Calcar Replacement Hip Stem are substantially equivalent to the features employed by the following predicate legally marketed devices:

- ▶ Calcar Replacement Stem: IOI - (510(k) #K945516);
- ▶ Omnifit Head/Neck Hip Stem: Osteonics Corporation (510(k) No. unknown to IOI);
- ▶ HNR (Head and Neck Replacement) Stem: Howmedica Corporation (510(k) No. K902712); and
- ▶ Cemented Calcar Stem: Depuy Inc. (510(k) No. unknown to IOI);

**Device Description:**

The Calcar Replacement Hip Stem employs a Sulzer 12/14 configured threaded trunnion for attachment to the IOI's femoral heads, including Biolox and Zirconia ceramic heads, featuring a Sulzer 12/14 configured threaded bore. The Biolox and Zirconia ceramic heads are available in two sizes, 28mm inner diameter (ID), and 32mm ID. The Biolox and ceramic bearing heads have been determined substantially equivalent by the FDA via 510(k) #'s K923934 and K942330.

The proximal body of the hip stem features an extraction hole in the anterior/posterior direction to facilitate removal of the hip stem if revision becomes necessary. The proximal body of the hip stem features a slotted flange which allows the surgeon the option of wiring the trochanter. The Calcar Replacement Hip Stem employs a keel below the proximal-medial flange for enhanced rotational stability.

The grit blasted distal portion of the hip stem employs two medial longitudinal grooves and is oval shaped. The grit blasted surfaces provide enhanced interdigitation with bone cement. The Calcar Replacement Hip Stem is available with a distal hole for optional use with the PMMA canal centralizer.

**Intended Use:**

The Calcar Replacement Hip Stem is intended for use in treatment of intertrochanteric, comminuted, or femoral neck fracture; trochanteric non-union; erosion of calcar or femoral neck, and; revision total hip arthroplasty involving bone loss in the proximal femur or tumors. In addition, the Calcar Replacement Hip Stem like the predicate IOI and competitive hip stems is intended for cemented application in cases of total hip arthroplasty.

1. Patient conditions of intertrochanteric, comminuted or femoral neck fracture
2. Trochanteric nonunion
3. Erosion of the calcar or femoral neck
4. Revision total hip arthroplasty involving bone loss in the proximal femur
5. Tumors.

Patient selection will be largely dependent on patient's age, general health, conditions of available bone stock, any prior surgery and anticipated further surgeries. Prosthetic replacement is generally indicated only for patients who have reached skeletal maturity.

**Summary of  
Technological  
Characteristics:**

A side by side tabular comparison of the characteristics of the Calcar Replacement Hip Stem to those of the currently marketed IOI and competitive devices follows:

<u>Characteristics</u>	<u>Subject Device</u>	<u>Predicate Devices</u>		
		<u>Calcar Replacement Stem</u>	<u>Omnifit Head/Neck Hip Stem</u>	<u>Head/Neck Replacement System</u>
Manufacturer	Intermedics Orthopedics, Inc.	Intermedics Orthopedics, Inc.	Osteonics Corporation	Howmedica Inc.
510(k) No.	-	K945516	K902712	Unknown to IOI
Intended Use	Cemented	Cemented	Cemented	Cemented
Material	Forged/Wrought CoCr Alloy	Cast CoCr Alloy	Cast CoCr Alloy	CoCr Alloy
Slotted Flange	Yes	Yes	Yes	Yes
Extraction Hole	Yes	Yes	Yes	Yes
Collar	Yes	Yes	Yes	Yes
Proximal Medial Keel	Yes	Yes	Yes	Yes
Distal Hole	Yes	Yes	Yes	Yes
Stem length	140 and 160 mm	140 and 160 mm	120, 140, 160, and 190 mm	135, 165, and 185mm