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Summary of Safety and Effectiveness Data
for the
ULTIMA® Total Hip System
Cemented Calcar Replacement Femoral Stem

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Name of Device

Proprietary Name: Ultima® Cemented Calcar Replacement Stem
Common Name: Cemented Calcar Replacement Femoral Stem
Classification Name: Hip/joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II by 21 CFR 888.3350
Product Code: 87 JDI
Owner/Operator No.: 9001269

Device Classification

This device has been placed in Class II for Hip joint metal/polymer semi-constrained cemented prosthesis per 21 CFR § 888.3350.

Statement of Substantial Equivalence

The Ultima Cemented Calcar Replacement Femoral Stem is substantially equivalent in function to both the Howmedica HNR with Porus Coating, cleared for marketing under premarket notification #K922503 (September 21, 1992) and the Osteonics OmniFit Head/Neck Stem, cleared for marketing under premarket notification #K902712 (August 9, 1990). Further, the Cemented Calcar Replacement Femoral Stem is substantially equivalent in material and design to the ULTIMA Cemented Long Stem Femoral Component, previously cleared for marketing under premarket notification #K952859 (January 31, 1996).

The subject device is composed of similiar materials to the predicate devices mentioned above. Further, the intended use, design, and manufacture of the The Ultima Cemented Calcar Replacement Femoral Stem are substantially equivalent to those currently distributed. Additionally, the packaging and method of sterilization utilized for the The Ultima Cemented Calcar Replacement Femoral Stem are the same as those used for the previously mentioned predicate devices.

Indications for Use

The Ultima Total Hip System - Cemented Calcar Replacement Femoral Stem is indicated for use in total, partial, or revision hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, traumatic femoral fractures, and nonunion of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis, and disability due to previous fusion, where bone stock is inadequate for other reconstructive techniques.

The Ultima Cemented Calcar Replacement Stem is indicated for use only with PMMA bone cement.

Physical Description

The Ultima calcar replacement stem is a cemented femoral component for use in total or partial hip arthroplasty procedures. The stems are available in standard and long lengths. The standard length size range includes 3 base stem sizes, each available in 3 body lengths. The 3 base sizes are also each available in right and left long stem components; which are anatomically bowed. Also, the stems are available in 2 trunnion taper designs, i.e., 10/12 and 12/14.

The stem body design is derived from that of the primary Ultima stems #K924379. The proximal body of the Ultima cemented calcar stem, below the horizontal flange, is identical to that of the primary Ultima stems of equivalent size.

The Ultima calcar replacement stem features a vertical and horizontal flange, the former to provide support for the deficient or fractured greater trochanter and the latter to anatomically cap the resected calcar surface. The vertical flange has grooves located along its anterior and posterior edges to provide a constraint in cases where cables/wires are used. The lateral face of the vertical flange features a macrotextured surface finish to provide some resistance to movement of the greater trochanter against the lateral flange.

A 2-lobed A/P hole is provided proximal to the horizontal flange to enabling passing a cable/wire through the stem when it is necessary to anchor the greater trochanter and/or a proximal bony fragment to the stem. The medial aspect of the stem immediately proximal to the horizontal flange features a gentle radius to enable cabling/wiring around the stem if necessitated.

The distal aspect of the standard length stems are fluted to provide resistance to rotational movement of the stem. The standard length stems also feature a distal hole to accept an optional PMMA distal centralizer component. The long stems are anatomically bowed to pass the isthmus and thereby bypass actual or potential bony defects.