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**SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION
FOR THE PREMARKET NOTIFICATION FOR THE
AuRA™ Hip System
CALCAR REPLACEMENT FEMORAL STEM**

Exactech®, Inc.

Establishment Registration Number 1038671

The AuRA™ Calcar Replacement Femoral Stems are made of similar materials and are of similar design to prostheses that were on the market before May 28, 1976. Additionally, the calcar stems are of similar design to other cemented femoral components on the market that have been determined to be equivalent to devices on the market prior to May 28, 1976. These predicates include, but are not limited to: Howmedica hnr Head/Neck Replacement System.

Exactech, Inc. has supplied advertisements, brochures and/or catalog information from the company to the FDA as evidence of equivalency. This literature is in the public domain. In addition, Exactech has provided the FDA design drawings, material specifications and dimensional images of the AuRA™ stems.

This device is appropriately placed in FDA classification: Prosthesis, Hip, Femoral Component, Cemented, Metal. Number 87JDG, Class II device, under 21 CFR 888.3360.

1. Device Description/ Design Rationale

The collar of the calcar replacement stem differentiates itself from all other cemented femoral components in that it provides a horizontal and vertical collar type platform for the best load transfer in a compromised femoral situation. A cemented primary or long stem device typically has a collar designed at some angle to the femoral centerline whereby a bone loading platform can be established at the optimum resection location. In many instances, this ideal position has been compromised and an implant surface that is horizontally perpendicular to and vertically parallel to the femoral centerline is preferred for optimal axial load transfer to the bone and appropriate trochanteric fixation can be achieved.

The surface finish is dominated by an overall satin, glass bead blast everywhere except on the taper. A secondary grit blast is performed on portions of the proximal region of the implant.

A complete instrumentation and trial system is available to assist in accurate implantation of the AuRA™ Calcar Replacement Femoral Stem.

Similarities/Dissimilarities to the Howmedica hnr Hip System:

The Exactech AuRA™ Calcar Replacement Femoral Stem is similar to the Howmedica hnr Femoral Stem in the type of finish used: both have a dual grit blast. Both prosthesis feature derotation keels and calcar slots. Both offer distal centralization. Both the Exactech AuRA™ and the Howmedica hnr use modular femoral heads.

The Exactech AuRA™ Calcar Replacement Femoral Stem is dissimilar to the Howmedica hnr in the material used: the Exactech Femoral Stem is manufactured from forged cobalt chrome as apposed to the cast cobalt chrome used in the Howmedica hnr Femoral Stem. The Exactech stem has a straight body: the Howmedica stem is available with both a straight and curved body. The Hip Systems differ in the sizes offered: the smallest calcar flange length offered by Exactech is a 44mm, while the Howmedica system has a 33mm. The shortest body length offered by the Exactech system is 146mm, while the Howmedica system has a body length of 135mm. The Exactech Calcar Replacement Femoral Stem design has no longitudinal distal flutes featured in the Howmedica prosthesis. The Exactech stem features both slots and holes for wire fixation: the Howmedica femoral stem has only slots

2. Material Specifications

The AuRA™ Calcar Replacement Femoral Stem is made from forged cobalt chrome which meets ASTM specification F799-95.

3. Mechanical Testing

The forged cobalt chromium alloy exhibits mechanical properties in excess of 170,000 psi ultimate tensile strength, 120,000 psi yield strength, 12% elongation, and 12% reduction of area and a minimum of 35 hardness, Rc.

In addition, fatigue testing results have been favorable for this type of device.

4. Range of Motion and Constraint

The AuRA™ Calcar Replacement Femoral Stem is designed to mate with the appropriate femoral stem size dictated by the patient's anatomy. Likewise, the patient's range of motion and constraint is limited by the anatomy.

5. Biocompatibility

According to ASTM F799-95, the material in this specification has been evaluated for biocompatibility and corrosion resistance and has been found comparable to material conforming to specification F75. The results of these studies and the clinical history indicate a well-characterized level of local biological response.

6. Sterilization

The AuRA™ Calcar Replacement Femoral Stem will be supplied sterile. The components will be sterilized in the final, sealed packages by gamma irradiation at a contract sterilization facility. The sterilization protocol will be based on the Guidelines for Radiation Sterilization of Medical Devices, issued by the Association for Advancement of Medical Instrumentation Process Control. The devices are not claimed to be pyrogen free.

7. Utilization of Implantation

Selection of the component is made by the surgeon in relationship to the requirements of the patient. The surgeon should become thoroughly familiar with the technique of implantation of the prosthesis by: 1) appropriate reading of the literature and 2) training in the operative skills and techniques required for hip arthroplasty surgeries.

8. Indications

The Exactech AuRA Calcar Replacement Femoral Stem is indicated for use in skeletally mature patients in whom the calcar region is missing due to a failed previous total hip replacement as a result of osteoarthritis, osteonecrosis, rheumatoid arthritis or congenital hip dysplasia. It is also potentially indicated for use in post-traumatic degenerative problems.

FOR CEMENTED USE ONLY

9. Contraindications

Use of the AuRA™ Calcar Replacement Femoral Stem is contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in patients with neuromuscular disorders that do not allow control of the hip joint, and in patients whose weight, age or activity level would cause the surgeon to expect early failure of the system.