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**SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION
FOR THE PREMARKET NOTIFICATION FOR THE**

**AuRA™ Hip System
Cemented Femoral Stem
Cemented Long Femoral Stem**

Exactech®, Inc.

Establishment Registration Number 1038671

The AuRA™ Cemented 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 femoral 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:

- Smith & Nephew Orthopaedics
Spectron® Total Hip System

Exactech, Inc. has supplied advertisements, brochures and/or catalog information from these companies 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 87JD~~0~~^{I P2}, Class II device, under 21 CFR 888.3360.

1. Device Description/ Design Rationale

The AuRA™ femoral stem is manufactured of forged Cobalt Chromium, ASTM F-799-95. The stem body has a trapezoid cross section with a lateral flange in the proximal half and has a grit and bead blast finish. The medial aspect of the stem is defined by broad radii in both planes and the stem body is tapered over the entire length in both the anterior/ posterior and the medial/lateral direction. The neck and collar region of the stems features anterior and posterior neck flats for a maximized range of motion. A wide collar maximizes load transmission to the calcar. Each stem body has a proximal, longitudinal cement interdigitation groove on the anterior and posterior face. There are also locating holes to accept optional centralizers.

The Proximal Centralizer is an injection molded polymethylmethacrylate modular component for use exclusively with the AuRA™ Hip System. It is similar to the Exactech Distal Centralizer previously released for use with the Exactech Cemented Hip. The Proximal Centralizer is a cement spacer which provides a mechanism by which the surgeon can centrally position the proximal aspect of the stem body in the prepared femoral canal.

A taper connection matches all of the Exactech femoral head components and the Exactech Unipolar Endoprosthesis.

The cobalt chrome geometry of the AuRA™ femoral stem prostheses has had many predecessors since the use of the Moore prosthesis over 50 years ago. The manufacturing advances in materials technology has led to devices which exhibit increased structural strength. The AuRA™ Hip System is patterned after other clinically successful cemented femoral designs and clinical results have been reported to be effective.

The AuRA™ Cemented Femoral Stem is similar to the Spectron® Hip System in that both have two levels of surface finish; proximal grit blast and overall satin bead blast. Both have fully tapered stem bodies and have modular taper connections for femoral heads. Both hips are manufactured from forged cobalt chrome .

The AuRA™ Hip System is dissimilar to the Spectron in that the AuRA™ offers different body sizes and neck lengths than the Spectron Hip System. The Spectron stems have variable neck angles and the AuRA™ stems have a single neck angle. Spectron's round medial collar runs completely to the back of the stem, whereas the AuRA™ stem collar truncates at about 1/3 of the stem body width. The AuRA™ stem has a proximal cement groove and lateral flange and Spectron has neither. The Spectron does not have a proximal or distal centralization locator.

There is no proximal centralizer in the Spectron System.

A complete instrumentation and trial system is available to assist in accurate implantation of the AuRA™ Hip System.

2. Material Specifications

The AuRA™ Femoral Stem is made from forged cobalt chrome which meets ASTM specification F799-95. The material chemical composition of cast cobalt chrome is based on ASTM F799-95.

The Proximal Centralizer is manufactured from injection molded polymethylmethacrylate (PMMA) which meets ASTM 451-86.

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. The material and manufacturing methods for the blast finish are identical to the ones used for the Exactech OPTEON® Hip. The Finite Element Analysis test results were favorable.

4. Range of Motion and Constraint

The AuRA™ 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.

Polymethylmethacrylate (ASTM 451-86) has been used for decades in joint replacement and is demonstrated by historical data to be biocompatible.

6. Sterilization

The AuRA™ Femoral Stem and the optional Centralizer 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 AuRA™ Cemented Femoral Stem and Cemented Long Femoral Stem are indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, osteonecrosis, congenital hip dysplasia, rheumatoid arthritis and/or post-traumatic degenerative problems. It is also potentially indicated for revision of failed previous reconstruction where sufficient bone stock is present.

FOR CEMENTED USE ONLY ✓

9. Contraindications

Use of the AuRA™ 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.