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**SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION
FOR THE PREMARKET NOTIFICATION FOR THE
OPTEON® Unipolar Endoprosthesis**

Exactech®, Inc.

Establishment Registration Number 1038671

The Opteon® Unipolar Endoprosthesis is made of similar materials and is of a similar design to prostheses that were on the market before May 28, 1976. Additionally, the Opteon® Unipolar is of a similar design to other 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:

- Corin® Unipolar Endoprosthesis #K881288
- Howmedica Unitrax® Unipolar System #K902365

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 photos of the Opteon Unipolar Endoprosthesis.

This device is appropriately placed in FDA classification:
Prosthesis, Hip, Hemi, Femoral, Metal Ball. Number 87LZY, Class II device, under 21 CFR 888.3560.

1. Device Description

The OPTEON Unipolar Endoprosthesis is a polished, truncated sphere made of cast cobalt chrome, ASTM F75. The high tolerance taper connection machined at the base of each unipolar component will mate with all Exactech femoral hip stems.

The external geometry approximates the shape of the normal femoral head and is intended for use in hemiarthroplasty. The modular system allows for future total hip arthroplasty without removal of the femoral stem.

The cast cobalt chrome geometry of the Exactech unipolar prosthesis has had many predecessors since the use of the Moore prosthesis over 50 years ago. The manufacturing advances in casting and materials technology has led to devices which exhibit increased structural strength and highly polished surfaces for decreased surface friction. The OPTEON Unipolar is patterned after other clinically successful unipolar designs. Clinical results of the Unipolar device has been reported to be effective.

The OPTEON Unipolar is similar to the Corin Unipolar and the Howmedica Unipolar in material, finish, and spherical design. Both the Opteon and the Corin Unipolar have a taper machined into it that will mate directly to the femoral components. Both outside geometries are essentially truncated spheres. Both are manufactured from ASTM F-75 Cobalt Chrome.

The Exactech Opteon Unipolar device is similar to the Howmedica design in that both utilize metal spheres. The Exactech Unipolar is dissimilar from the Howmedica Unitrax® Unipolar System in the way the Unitrax component connects to the femoral stem. The inner portion of Howmedica's Unipolar contains a polyethylene insert which allows the intraoperative press fit assembly of a metal, tapered neck sleeve. Howmedica's Unipolar also offers various sizes of tapered neck sleeve choices.

A complete instrumentation and trial system is available to assist in accurate implantation of the Exactech OPTEON Unipolar Endoprosthesis.

2. Material Specifications

The OPTEON Unipolar component is made from cast cobalt chrome which meets ASTM specification F75-87. The material chemical composition of cast cobalt chrome is based on ASTM F75-87.

3. Mechanical Testing

The cast cobalt chromium alloy exhibits mechanical properties in excess of 95,000 psi tensile strength, 65,000 psi yield strength, 8% elongation, and 8% reduction of area.

4. Range of Motion and Constraint

The Exactech OPTEON Unipolar Endoprosthesis 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 F75-87, the material in this specification has been evaluated for biocompatibility. The results of these studies and the clinical history indicate a well-characterized level of local biological response.

6. Sterilization

The OPTEON Unipolar Endoprosthesis will be supplied sterile. They will be sterilized in their 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.

7. Utilization of Implantation

Selection of the OPTEON Unipolar 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 OPTEON Unipolar Endoprosthesis is for use with a modular femoral stem when hemiarthroplasty is indicated. The change to a total hip replacement can then be accomplished in the future without removing the femoral stem.

The OPTEON Unipolar is indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, osteonecrosis, rheumatoid arthritis and/or post-traumatic degenerative problems. It is also indicated for use in replacement of the femoral head following femoral neck fracture .

9. Contraindications

Use of the OPTEON Unipolar 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. The Unipolar is also contraindicated for use in patients with evidence of degenerative changes in the acetabulum and/or pelvic fractures.