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510(K) Summary

SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION IN THE PREMARKET NOTIFICATION FOR THE EXACTECH TOTAL HIP SYSTEM: 22mm FEMORAL HEAD

Exactech, Inc.

Establishment Registration Number 1038671

The Exactech 22mm Femoral Head is made of similar materials and is of a similar design to prostheses that were on the market before May 28, 1976. Additionally, the 22mm Femoral Head is of 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:

- Orthomet
- Zimmer-Charnley Type Total Hip
- Exactech® Femoral Heads

In addition, Exactech provided to the FDA, design drawings, and material specifications characterizing the 22mm Femoral Head

The Food and Drug Administration, in rules listed in the Federal Register, Friday, September 4, 1987, as Hip Joint Metal/Polymer Semi-Constrained Prosthesis, Section 888.3350 and Docket No. 78N3075, as a class II Device.

Design Considerations

The Exactech 22mm Femoral Head is sized in three neck lengths: short (-3mm), standard (+2mm), long (+8mm). It is available in 22mm diameter. The femoral head is made of cobalt chromium alloy, a preferred metal alloy for bearing with The Ultra High Molecular Weight Polyethylene (UHMWPE), found in the acetabular components. The femoral head mates with the femoral stem by its precise internal taper lock. In addition, its overall design is similar to those used by Charnley and others since the early introduction of Total Hip Arthroplasty and assures adequate component thickness as put forth by Bartel for such components.

Design Parameters

The Exactech Total Hip System: 22mm Femoral Head consists of various neck lengths and is made from forged high strength cobalt chromium. The components are available in a range of sizes to fit varying anatomical requirements. The device is designed for use with all Exactech femoral components. A complete trial set and instrumentation is available to assist in accurate implantation of the prosthetic components. Design drawings are typical for such components that have been used in the industry since their introduction by Charnley in the late '60's.

Material Specifications

The Exactech 22mm Femoral Head is manufactured from wrought high strength cobalt chromium corresponding with ASTM F90-87.

Biocompatibility

Cobalt Chromium has a long history of use in orthopaedic applications. Its biological response has been well characterized by a history of clinical studies (Charnley, J., Cupiz, A., "The Nine and Ten Year Results of the Low Friction Arthroplasty of the Hip", Clinical Orthopaedics, Vol 95, No. 9, 1973.; Halley, D., Charnley, J. "Results of Low Friction Arthroplasty in Patients 30 Years of Age and Younger", Clinical Orthopaedics, No. 112, October, 1975 and Mirra, J., Amstutz, H,. Matos, M., and Gold, R., "The Pathology of Joint Tissues and Its Clinical Relevance in Prosthesis Failure", Clinical Orthopaedics, No. 117, June, 1976) and by laboratory studies (Turner, J., Lawrence, W., and Autian, J., "Subacute Toxicity Testing of Biomaterials Using Histopathologic Evaluation of Rabbit Muscle Tissue," Journal of Biomedical Materials Research, Vol 7, 1973. Compatibility of Biocompatibility of Materials for Total Joint Replacement". Journal of Biomed. Mater. Research, Vol 10, No.2, 1976.). These tests include data on human and animal performance and show that the tissue exhibits excellent biocompatibility.

See Volume II for References

Sterilization

The Exactech 22mm Femoral Head will be sterilized by gamma irradiation. The Sterility Assurance Level (SAL) is 10^{-6}. Exactech utilizes Method 3, Protocol B from the "AAMI Guideline for gamma radiation sterilization" for the sterility dose setting and validation procedure.

Utilization and Implantation

Selection of the Exactech Total Hip System: 22mm Femoral Head depends on the judgement of the surgeon in relationship to the requirements of the patient. The surgeon should become thoroughly familiar with the technique of implantation by appropriate reading of the literature, and training in the operative skills and techniques required for total hip arthroplasty surgery.

Indications

The Exactech Total Hip System: 22mm Femoral Head is 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 reconstructions where sufficient bone stock is present.

Contraindications

Use of the Exactech 22mm Femoral Head is contraindicated in patients with active infection, patients without sufficient bone stock to allow appropriate insertion and fixation of the prosthesis, in 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 to the system.