EXACTECH®

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510(k) Summary

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510(K) Summary

SUMMARY OF THE SAFETY AND EFFECTIVENESS INFORMATION IN THE PREMARKET NOTIFICATION FOR THE EXACTECH ALL POLY ACETABULAR CUP

Exactech, Inc.

Establishment Registration Number 1038671

The Exactech All Poly Acetabular Cup is made of similar materials and is of a similar design to prostheses that were on the market before May 28, 1976. Additionally, the All Poly Acetabular Cup 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:

- T.A.R.A. by DePuy
- Dual Lock by DePuy
- New England Baptist System by DePuy
- Triad System by Johnson and Johnson
- Modular Hip System by Richard
- Spectron Total Hip System by Richards
- Exactech® All Poly Cup

In addition, Exactech provided to the FDA, design drawings, and material specifications characterizing the All Poly Acetabular Cup.

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 All Poly Cup has a geometry typical of currently used prostheses that incorporate an outer interlock surface intended for cemented use. The poly surface finish at the head/cup articulation is equivalent to all approved components currently sold by Exactech. It is manufactured to the same standards as detailed in Exactech's components drawings and specifications for all polyethylene acetabular components. 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 All Poly Acetabular Cup consists of various sizes and is made from Medical Grade Ultra High Molecular Weight polyethylene (UHMWPE) with a Cobalt Chrome F 90-87 radiographic marker wire. The component is produced in various inside and outside diameters and accommodates numerous femoral head sizes. The device is designed for use with all Exactech femoral components and femoral heads. 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.

Under this premarket notification, the device is available in outside diameters ranging from 42mm through 70mm with internal diameters accommodating femoral head sizes in 22mm, 26mm, 28mm and 32mm.

Material Specifications

The Exactech All Poly Acetabular Cup is manufactured from Medical Grade Ultra High Molecular Weight Polyethylene corresponding with ASTM F648-84. It also has a Radiographic marker wire made from Cobalt Chrome corresponding to ASTM F90-87.

Biocompatibility

Ultra High Molecular Weight Polyethylene 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.

Sterilization

The Exactech All Polyethylene Cups 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 All Polyethylene Acetabular Cup 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 All Polyethylene Acetabular Cup is indicated for use in skeletally mature individuals undergoing primary surgery for total hip replacement due to osteoarthritis, osteonecrosis, congenital hip dysplasia, rheumatoid arthritis, ankylosing spondylitis and/or posttraumatic degenerative problems. It is also potentially indicated for revision of failed previous reconstructions where sufficient bone stock is present.

Contraindications

Use of the Exactech® All Poly Acetabular Cup 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.