

K955767

Smith & Nephew Orthopaedic Implant Division

a division of Smith & Nephew Richards Inc.
1450 Brooks Road, Memphis, TN 38116
Telephone: 901-396-2121

APR - 8 1996

Smith + Nephew

Thomas L. Craig
Director, Regulatory and Clinical Affairs
Orthopaedics
Smith & Nephew Richards Inc.
1450 Brooks Road
Memphis, TN 38115
Telephone: (901) 396-2121
Fax: (901) 398-5146

Summary of Safety and Effectiveness
Smith & Nephew Richards Inc.
Cofield Modular Shoulder System
October 20, 1995

Trade Name - Cofield Modular Shoulder System
Common Name - modular shoulder system
Classification Name - Shoulder Joint Metal/Polymer Semi-Constrained Cemented
Prosthesis 21 CFR 888.3660

Substantial Equivalent Information

The Cofield Modular Shoulder System is similar to the following shoulder systems:

1. Biomet Biomodular Total Shoulder
2. DePuy Global Total Shoulder
3. Orthomet 3M Neer II and Modular Shoulder
4. Zimmer Fenlin Total Shoulder
5. Kirschner Modular II-C
6. Intermedics Select Shoulder System

All the devices listed above are indicated for total shoulder replacement and are indicated for use with cement. They are all similar to the design of the Cofield Modular Shoulder. The safety and effectiveness of the Cofield Modular Shoulder are based on the long history of use of these devices in the market place.

Device Description

The Cofield Modular Shoulder System consists of the following components:

Stem component
Head component
Glenoid UHMWPE component

The humeral components are fabricated from Co-Cr-Mo. The porous coating on the undersurface of the collar of the stem is fabricated from Co-Cr-Mo beads. The glenoid component is manufactured from UHMWPE.

Indications for Use

The Cofield Modular Shoulder System is indicated for the following use:

Proximal Humeral Prosthesis

1. Complex, acute fractures or fracture-dislocations of the humeral head (e.g., the four-part injuries in the Neer classification, or headsplitting, or head impression fractures).
2. Complex, chronic fractures or fracture-dislocations of the humeral head with malunion, nonunion of a small osteoporotic head fragment, or chronic dislocation with loss of humeral head cartilage, or large impression fractures.
3. Avascular necrosis with intact glenoid cartilage.
4. Selected patients with arthritis who do not have adequate scapular bone to support a glenoid component or who must engage in moderately heavy activities.

Total Shoulder Arthroplasty

Severe destruction of the glenohumeral articular surfaces with intractable chronic pain in rheumatoid arthritis, juvenile rheumatoid arthritis, osteoarthritis, traumatic arthritis, cuff tear arthroplasty, ancient septic arthritis, avascular necrosis with secondary glenoid changes, radiation necrosis, and other failed reconstructive procedures.

The device is intended only for use with bone cement and is a single use device.

Mechanical Testing

Mechanical testing was performed according to the requirements of FDA guidance documents and met or exceeded acceptable performance.