APR - 5 2001

K010664
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SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor:	Biomet, Inc. Airport Industrial Park Warsaw, Indiana 46580
Contact Person:	Sara A. Bailey (219) 372-1568
Device:	Copeland Resurfacing Humeral Heads
Classification Name:	Shoulder joint metal/polymer/ non-constrained cemented prosthesis
Device Product Code:	KWT (21 CFR 888.3650)

Intended Use:
The Copeland Resurfacing Humeral Heads are indicated for the following conditions where the humeral head and neck are of sufficient bone stock and there is presence of an intact or reconstructable rotator cuff which is necessary for proper functioning and dislocation resistance:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis.
2) Rheumatoid arthritis
3) Correction of functional deformity
4) Reconstructable rotator cuff
5) Treatment of fractures of the humeral head
6) Traumatic arthritis

For cemented use only.

Device Description:
These devices are cemented and are designed to maintain maximum bone stock by removing minimal bone and replacing only the defective surface. Copeland Resurfacing Humeral Heads can be used in hemi- or total shoulder replacement surgical procedures. By preserving the bone stock, this device gives a patient an alternative to other total shoulder devices where more bone is removed.

The humeral head components are available in four sizes – small, medium, large, and extra-large. The small, medium, and large humeral heads have the same radius of curvature, but the heights differ to cater for the range of anatomical sizes and offsets. The extra-large head has a larger radius of curvature to accommodate a patient with larger bone stock. The stem is tapered and fluted to provide maximum stability in the

humerus. The components are manufactured from cobalt-chrome-molybdenum alloy (ASTM F-75) and coated with MacroBond™ (Ti-Al-4V, ASTM F-1580) on the non-articulating surface.

The small, medium, and large humeral head components can be used with Biomet's BioModular Glendoids or Integrated Glenoids. The extra-large head can only be used with Biomet's BioModular Glenoids due to the larger spherical radius.

Potential Risks: The potential risks associated with this device are the same as with any joint replacement device. These include, but are not limited to:

1) Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process. Particulate wear debris and discoloration from metallic and polyethylene components of joint implants may be present in adjacent tissue or fluid. It has been reported that wear debris may initiate a cellular response resulting in osteolysis or osteolysis may be a result of loosening of the implant.
2) Early or late postoperative infection and allergic reaction.
3) Intraoperative bone perforation or fracture may occur, particularly in the presence of poor bone stock caused by osteoporosis, bone defects from previous surgery, bone resorption, or while inserting the device.
4) Loosening or migration of the implants can occur due to loss of fixation, trauma, malalignment, bone resorption, excessive activity.
5) Prearticular calcification or ossification, with or without impediment of joint mobility.
6) Inadequate range of motion due to improper selection or positioning of components.
7) Undesirable shortening of limb.
8) Dislocation and subluxation due to inadequate fixation and improper positioning. Muscle and fibrous tissue laxity can also contribute to these conditions.
9) Fatigue fracture of component can occur as a result of loss of fixation, strenuous activity, malalignment, trauma, non-union, or excessive weight.
10) Fretting and crevice corrosion can occur at interfaces between components.
11) Wear and/or deformation of articulating surfaces.
12) Accelerated wear of glenoid articular cartilage.
13) Postoperative bone fracture and pain.

Predicate Device(s): Copeland Resurfacing Heads, K003044

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Sara A. Bailey
Regulatory Affairs Specialist
Biomet, Inc.
Airport Industrial Park
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K010664
Trade Name: Copeland Resurfacing Humeral Heads
Regulatory Class: II
Product Code: HSD and KWT
Dated: March 2, 2001
Received: March 6, 2001

Dear Ms. Bailey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) Number (if known) : K010664

Device Name: Copeland Resurfacing Humeral Heads

Indications For Use:

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4) Reconstructable rotator cuff
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6) Traumatic arthritis

For cemented use only.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010664

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use (Optional Format 1-2-96)