K010657

SEP 1 4 2001

BIOMET

CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Sponsor:	Biomet, Inc. Airport Industrial Park Warsaw, Indiana 46580
Contact Person:	Sara B. Shultz Telephone: (219) 267-6639 Fax: (219) 372-1683
Device:	Copeland™ MB Resurfacing Humeral Heads
Classification Name:	prosthesis, shoulder, hemi-, humeral, metallic, uncemented
Device Product Code:	HSD (21 CFR 888.3690) MBF (unknown, recently down classified)

Legally Marketed Devices To Which Substantial Equivalence is Claimed: Copeland™ Resurfacing Heads (K003044), Bi-Polar Shoulder (K002998), Bi-Polar Shoulder System (K991585), and Bio-Modular® Shoulder System (K992119).

Intended Use: The Copeland™ MB 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 uncemented use only.

Device Description: These devices are intended for use as a cementless fixation humeral replacement system that requires minimal bone resection. Copeland™ MB Resurfacing Humeral Heads can be used in hemi- or total shoulder replacement surgical procedures in

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Patients experiencing pain or disability of the gleno-humeral joint. By preserving the bone stock, this device gives a patient an alternative to other total shoulder devices where more bone is removed. This device can easily be revised to a longer stemmed prosthesis if necessary due to the initial bone preservation.

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 have a thin layer of plasma spray coating known as MacroBond™ on the non-articulating surface. There is a depression in the surface of the inner spherical radius of the head. This depression is intended for the location of the MacroBond™ Coating.

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

Summary of Technologies: The Copeland™ MB Resurfacing Humeral Heads have the same design as the predicate Copeland™ Resurfacing Heads. The predicate devices are porous coated and cleared for cemented use, whereas, this submission contains a device with a MacroBond™ coating indicated for uncemented use. Clinical data was supplied to address these differences.

Non-Clinical Testing: Finite Element Analysis was done to compare the Copeland™ MB Resurfacing Humeral Heads to the predicate, Copeland™ Resurfacing Heads. The MacroBond™ coating was characterized by performing various mechanical tests.

Clinical Testing: Since 1990, 103 resurfacing heads have been implanted in cementless surface replacement arthroplasty of the shoulder. The minimum follow-up was 2 years. These clinical results provide data that demonstrates the substantial equivalence of the Copeland™ MB Resurfacing Humeral Heads

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 4 2001

Ms. Sara B. Shultz
Regulatory Specialist
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K010657/S001
Trade/Device Name: Copeland™ MB Resurfacing Humeral Heads
Regulation Number: 21 CFR 888.3690
Regulation Name: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: Class II
Product Code: HSD
Dated: June 14, 2001
Received: June 18, 2001

Dear Ms. Shultz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MD

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) : K010657

Device Name: Copeland™ MB Resurfacing Humeral Heads

Indications For Use:

The Copeland™ MB 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:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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

510(k) Number # K010657