DEC 1 3 2002

K023063
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SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Patricia Sandborn Beres
Telephone: (574) 267-6639

Proprietary Name: Comprehensive Humeral Fracture Stems

Common Name: Humeral Stem

Classification:
- Shoulder joint metal/polymer non-constrained cemented prosthesis (888.3650).
- Shoulder joint metal/polymer/metal non-constrained or semi-constrained porous coated uncemented prosthesis (888.3670).
- Shoulder joint metal/polymer semi-constrained cemented prosthesis (888.3660)
- Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis (888.3690)

Device Classification: Class II

Legally Marketed Devices to which Substantial Equivalence is Claimed: DePuy Orthopaedics' Global® Shoulder- 510(k) K984541, Biomet, Inc.'s Bi-Angular Co-Cr Humeral Components- 510(k) K961571, Kirschner Shoulders With Titanium Plasma Spray- 510(k) K961260, and Bio-Modular Shoulder System- 510(k) K992119.

Device Description: The Comprehensive Humeral Fracture Stems consists of various lengths and can be provided with an Interlok® finish for cement fixation or with a thin layer of plasma spray coating known as MacroBond™ for press-fit. The device is fluted distally which allows for a cement mantle and an increase in anti-rotational stability. The proximal body of the stem incorporates a reverse Morse taper for the Bio-Modular Heads and 4 fins, three of which include suture holes to facilitate multiple attachment sites for the bone. A collar also exists to minimize subsidence.

Indications for Use: The Comprehensive Humeral Fracture Stems are indicated for 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) Rheumatoid arthritis; 3) Revision where other devices or treatments have failed; 4) Correction of functional deformity; 5) Fractures of the proximal humerus, where other methods of treatment are deemed inadequate; and 6) Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

Summary of Technologies: The Comprehensive Humeral Fracture Stems - the materials, design, sizing, and indications are similar or identical to the predicate devices.

Non-Clinical Testing: Mechanical Testing and a Finite Element Analysis determined that the Comprehensive Humeral Fracture Stems presented no new risks and were, therefore, substantially equivalent to the predicate devices.

Clinical Testing: No clinical testing was provided as a basis for substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 13 2002

Ms. Patricia Sandborn Beres
Senior Regulatory Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K023063
Trade/Device Name: Comprehensive Humeral Fracture Stems
Regulation Numbers: 21 CFR 888.3650; 21 CFR 888.3660; 21 CFR 888.3670; 21 CFR 888.3690
Regulation Names: Shoulder joint metal/polymer non-constrained cemented prosthesis; Shoulder joint metal/polymer semi-constrained cemented prosthesis; Shoulder joint metal/polymer/metal non-constrained or semi-constrained porous-coated uncemented prosthesis; Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Codes: KWT, KWS, MBF, HSD
Dated: September 12, 2002
Received: September 16, 2002

Dear Ms. Beres:

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), 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,

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): K023063

DEVICE NAME: Comprehensive Humeral Fracture Stems

INDICATIONS FOR USE:

The Comprehensive Humeral Fracture Stems are indicated for 1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis; 2) Rheumatoid arthritis; 3) Revision where other devices or treatments have failed; 4) Correction of functional deformity; 5) Fractures of the proximal humerus, where other methods of treatment are deemed inadequate; and 6) Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate.

The Interlok® finish Comprehensive Humeral Fracture Stems are intended for cemented use and the MacroBond™ coated Comprehensive Humeral Fracture Stems are intended for press-fit or cemented application.

for Mark N Milham

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

510(k) Number K023063

(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)