K030710

JUN - 4 2003

BIOMET
ORTHOPEDICS, INC.

Summary of Safety and Effectiveness

Applicant or Sponsor: Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0588

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist
Phone: (574) 267-6639
FAX: (574) 372-1683

Trade Name: Bio-Modular® Shoulder System

Common Name: Total shoulder replacement components

Classification Name:

1. Prosthesis, Shoulder, Non-constrained, Metal/Polymer, Cemented (21 CFR Section 888.3650)
2. Prosthesis, Shoulder, Semi-constrained, Metal/Polymer, Cemented (21 CFR Section 888.3660)
3. Prosthesis, Shoulder, Semi-constrained, Metal/Polymer, Uncemented (21 CFR Section 888.3670)
4. Prosthesis, Shoulder, Hemi-, Humeral, Metallic, Cemented or Uncemented (21 CFR Section 888.3690)

Legally Marketed Device to which Substantial Equivalence is claimed:

- The Bio-Modular® Shoulder System cleared by 510(k)s K872454, K915596, K992119, K992899 and K002998.
- The Gobal® Advantage Shoulder System cleared by 510(k)s K914695, K943300, K974044, K981487 and K011047.

Device Description: The Bio-Modular® Shoulder System consists of a humeral stem that is used in conjunction with a modular head and a metal backed or all polyethylene glenoid component. The Humeral Component is available in various lengths and porous coating levels. The Bio-Modular® Humeral stem features a bi-planer taper to promote stress transfer down the length of the stem. Each stem has a lateral fin to provide rotational stability. Holes in the fin provide the surgeon with the option of suture attachment during fracture reconstruction. A collar minimizes subsidence. The stems are circumferentially porous coated proximally to provide fixation by tissue ingrowth.

The proximal portions of the humeral stems feature a reverse Morse taper for attachment of the modular humeral head. Offset and Bi-Polar humeral heads are also available.

Modular, metal backed glenoid components are available for total shoulder replacement. These devices feature a central peg and the option of using screws for immediate fixation and porous coating to provide biological fixation when used without bone cement. All polyethylene glenoid components are available for cemented application.

Intended Use: The components of Bio-Modular® Shoulder System included in this submission are intended for total shoulder joint arthroplasty. Indications for use include:

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
6) Difficult clinical management problems, including cuff arthropathy, where other methods of treatment may not be suitable or may be inadequate

Devices with surface coatings are indicated for cemented or uncemented biological fixation application. Polyethylene glenoid components not attached to a metal back are indicated for cemented application only.

Summary of Technologies: The materials, surface finishes and processing of the Bio-Modular® Shoulder System are similar to the predicate device.

Non-Clinical Testing: Mechanical testing has demonstrated the device's ability to perform under expected clinical conditions. A full characterization of the porous surface has been provided.

Clinical Testing: None provided.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2003

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

Re: K030710
Trade/Device Name: Bio-Modular® Shoulder System
Regulation Number: 21 CFR 888.3650, 888.3660, 888.3670, 888.3690
Regulation Name: Shoulder joint metal/polymer non-constrained cemented prosthesis; Shoulder joint metal/polymer semi-constrained cemented prosthesis; Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis; and Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Regulatory Class: II
Product Code: KWT, KWS, MBF, and HSD
Dated: March 4, 2003
Received: March 6, 2003

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.

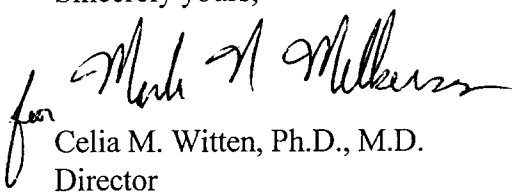
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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): K030710

Device Name: Bio-Modular® Shoulder System

Indications For Use:

1) Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
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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
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

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

510(k) Number K030710