K032895

NOV 2 0 2003

BIOMET
ORTHOPEDICS INC.

Summary of Safety and Effectiveness

Applicant/Sponsor: Biomet Orthopedics, Inc.

Contact Person: Patricia Sandborn Beres
Senior Regulatory Specialist

Proprietary Name: Bi-Angular® Shoulder System

Common or Usual Name: Total shoulder replacement components

Classification Name:

1) Prosthesis, Shoulder, non-constrained, 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 Devices To Which Substantial Equivalence Is Claimed:
Bio-Modular® Shoulder System – K030710
Proximal Humeral Component – K925613

Device Description: The Bi-Angular® Shoulder System is composed of a titanium alloy humeral stem with a modular humeral head which is designed to articulate with an all polyethylene glenoid component or the natural glenoid bone in a hemi-shoulder configuration. There is no linkage across the joint.

The proximally tapered, collarless stem follows the natural contours of the humeral canal thus promoting evenly distributed stress off-loading. Cylindrical distal stems fill the humeral canal. Proximal fins contribute to rotational stability while suture holes in the fins allow for proximal reconstruction of complex humeral fractures. During insertion, a K-wire can be placed into the version hole in the medial calcar region of the stem to allow exact version control of the component referencing off the patient's forearm.

Proximal porous coating on the humeral stem provides for biological fixation when used without bone cement. Non-porous humeral stems are available for cemented use.

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K032895

The humeral component utilizes a modular head which is taper-fit onto the stem at the time of surgery.

The all polyethylene glenoid component has an angled triangular shaped keel which can be trimmed during surgery.

Intended Use: The components of Bi-Angular® Shoulder System included in this submission are intended for hemi- or 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. Non-coated (Interlok®) and polyethylene components not attached to a metal backi are indicated for cemented application only.

Summary of Technologies: The materials, surface finishes and processing of the Bi-Angular® 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 was provided.

Clinical Testing: None provided

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 0 2003

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

Re: K032895
Trade/Device Name: Bi-Angular® Shoulder System
Regulation Number: 21 CFR 888.3670
Regulation Name: Shoulder joint metal/polymer/metal nonconstrained or semi-constrained porous-coated uncemented prosthesis.
Regulatory Class: II
Product Code: MBF
Dated: September 16, 2003
Received: September 17, 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 Miriam C. Provost

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): K032895

Device Name: Bi-Angular® Shoulder System

Indications For Use:

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
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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. Non-coated (Interlok®) devices and all polyethylene components are indicated for cemented application only.

(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

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

Over-The-Counter Use

(Optional Format 1-2-96)

510(k) Number K032895