DEC 0 2 2002

K023952 page 1/4

BIOMET

Summary of Safety and Effectiveness

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

Contact Person: Kacy Arnold, RN, MBA
Telephone: (574) 372-1644
Fax: (574) 372-1683

Proprietary Name: Modular Head Bone Screw

Common Name: Bone Screw

Classification Name: Screw, fixation, bone (888.3040)

Legally Marketed Devices to Which Substantial Equivalence is Claimed:
- Self-Countersinking Bone Screw (K013534)
- Synthes Sterile 3.0mm cannulated Screw (K962823)

Device Description:
This device is a metal screw shaft with a corresponding resorbable screw head. It also has an optional corresponding metal screw head for back-up purposes should the resorbable screw head become contaminated in the surgical environment.

Indications for Use: The Modular Head Bone Screw is indicated for the following conditions:
- Fixation of fractures in long bones such as the fibula, tibia, humerus, radius and ulna, as well as fractures in the patella
- Fixation of small bones such as those in the foot, ankle, wrist and elbow
- Ligament reconstruction
- Arthrodesis of the foot, ankle, wrist and elbow
- Small bone osteotomies
- Osteochondritis dissecans

Summary of Technologies: The Modular Head Bone Screw's technological characteristics are similar to or identical to the predicate devices.

Non-Clinical Testing: Mechanical testing was performed to establish substantial equivalence to the predicate devices.

Clinical Testing: Clinical testing was not used to establish substantial equivalence to predicate devices.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 2 2002

Biomet Orthopedics, Inc.
Kacy Arnold, RN, MBA
Regulatory Affairs Specialist
P. O. Box 587
Warsaw, Indiana 46581

Re: K022952
Trade/Device Name: Modular Head Bone Screw
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: September 4, 2002
Received: September 5, 2002

Dear Ms. Arnold:

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,

Miriam C. Provost

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

Enclosure

510 (k) Number (if known) : K022962

Device Name: Modular Head Bone Screw

Indications for Use:

The indications for the use of the Modular Head Bone Screw include:

- Fixation of fractures in long bones such as the fibula, tibia, humerus, radius and ulna, as well as fractures in the patella
- Fixation of small bones such as those in the foot, ankle, wrist and elbow
- Ligament reconstruction
- Arthrodesis of the foot, ankle, wrist and elbow
- Small bone osteotomies
- Osteochondritis dissecans

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 42 (Per 21 CFR 801.109) OR Over-The-Counter-Use N/A (Optional Format 1-2-96)

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

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510(k) Number K022962