K002515

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BIOMET

Summary of Safety and Effectiveness

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

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

Proprietary Name: Biomet Calcaneal Plate

Common Name: Bone Plate

Classification Name: Single/multiple component, metallic, bone fixation appliances and accessories.

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- Synthes Calcaneal Plate (K991407, K010518, K020401)
- Kirschner Small Fragment Fixation System (K864924)

Device Description: The Biomet Calcaneal Plate is an open structure bone plate with a cross-strut in the center manufactured from 316 LVM Stainless Steel. The device has 11 or 13 screw holes, depending on plate size, to ensure bone purchase of screws. The devices is slightly malleable, to conform to each patient's anatomy at the time of surgery. The device can also be cut in the operating room it achieve better fit.

The device is universal in design and therefore may be used on either the right or left foot. Three sizes are available, small, large and extra-large. A series of 3.5mm cortical screws are used in conjunction with the device.

Intended Use: 1) Intra-articular fractures of the calcaneus 2) Extra-articular fractures of the calcaneus and 3) Osteotomies of the calcaneus.

Summary of Technologies: The materials, surface finishes and processing of the device are similar to the predicate devices.

Non-Clinical and Clinical Testing: None provided

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P.O. Box 587
Warsaw, IN 46581-0587

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56 E. Bell Drive
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 2002

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

Re: K022515
Trade/Device Name: Biomet Calcaneal Plate
Regulation Number: 888.3030
Regulation Name: Single/multiple component, metallic, bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: July 29, 2002
Received: July 30, 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 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" (21 CFR 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 Mark N. Melkerson

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): K022515

Device Name: Biomet Calcaneal Plate

Indications For Use:

- Intra-articular fractures of the calcaneus
- Extra-articular fractures of the calcaneus
- Osteotomies of the calcaneus

for Mark N Milhous

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

510(k) Number K022515

(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)