K071498

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BIOMET®
ORTHOPEDICS, INC.

510(k) Summary
Subtalar Implant

Preparation Date: May 30, 2007
Applicant/Sponsor: Biomet Sports Medicine
Contact Person: Elizabeth Wray
Proprietary Name: Subtalar Implant
Common Name: Bone fixation device
Classification Name: Class II

- HWC- Smooth or threaded metallic bone fixation fastener (888.3040)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

Subtalar MBA® Implant System- K960692, 07/23/1996, Kinetikos Medical Incorporated (KMI)
Subtalar Arthrorisis Implant (Conical Subtalar Implant or CSI)- K032902, 12/15/2003, Nexa Orthopedics- Previously Futura Biomedical
Kalix Implant- K001231, 07/11/2000, New Deal- An Integra LifeSciences Company

Device Description:
The Subtalar Implant is a one-piece device comprised of titanium alloy or PEEK-OPTIMA® intended to be implanted into the sinus tarsi of the foot. The implant is available in eight sizes to accommodate a wide range of patient sizes. The device is used to stabilize the subtalar joint by restoring the arch of the foot and block anterior movement of the talus.

Indications for Use/Intended Use:
The Subtalar Implant is indicated for use in treating the hyperpronated foot by stabilizing the subtalar joint. It is intended to block forward, downward, and medial displacement of the talus, thereby limiting the excessive eversion of the hindfoot.
Examples include, but are not limited to:

- Symptomatic acquired flat foot treatment in children and adolescents
- Symptomatic congenital flexible flat foot
- Tarsal coalitions when associated with the flatfoot deformity
- Posterior tibial tendon dysfunction with supple feet
- Paralytic flat foot
- Subtalar Instability
- Severely pronated foot

Summary of Technologies:
The technological characteristics (materials, design, sizing, and indications) of the Subtalar Implant are similar or identical to the predicate device or other previously cleared devices.

Non-Clinical Testing: Mechanical testing confirmed that the Subtalar Implant meets the mechanical needs of the subtalar joint and will function within its intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

Mailing Address:
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Warsaw, IN 46581-0587
Toll Free: 800.348.9500
Office: 574.267.6639
Main Fax: 574.267.8137
www.biomet.com

Shipping Address:
56 East Bell Drive
Warsaw, IN 46582

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Sports Medicine, Inc.
% Ms. Elizabeth Wray
Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

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Re: K071498
Trade/Device Name: Subtalar Implant
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: May 30, 2007
Received: May 31, 2007

Dear Ms. Wray:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buehler
for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K071498

Indications for Use

510(k) Number (if known):_____

Device Name: Subtalar Implant

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- Severely pronated foot

Prescription Use YES (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use NO (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Buchman

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

510(k) Number K071498