JUL 1 2002

K021828

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BIOMET

CORPORATE HEADQUARTERS

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor:	Biomet Orthopedics, Inc. 56 East Bell Drive P.O. Box 587 Warsaw, Indiana 46581-0587
Contact Person:	Sara B. Shultz Biomet Manufacturing, Corp. 56 East Bell Drive P.O. Box 587 Warsaw, IN 46582 Phone: (574) 267-6639 FAX: (574) 372-1683
Proprietary Name:	Small Hammer Toe Pin
Common Name:	Arthrodesis pin
Classification Name:	Screw, Fixation, Bone, Non-spinal, non-metallic (888.3040).
Device Product Code:	87HWC

Legally Marketed Devices To Which Substantial Equivalence Is Claimed: Resorbable Hammer Toe Pin, Biomet, Inc. (K011137).

Intended Use: The Small Hammer Toe Pin is indicated for proximal interphalangeal (PIP) joint arthrodesis.

Device Description: The Small Hammer Toe Pin is made out of the oriented Lactosorb® material and is indicated for proximal interphalangeal joint (PIP) joint arthrodesis. LactoSorb® is a polyester derivative of L-Lactic and glycolic acids. Poly L-lactic/polyglycolic acid copolymer degrades and resorbs IN VIVO by hydrolysis into L-lactic and glycolic acids, which are then metabolized by the body. The device has threads on one end and barbs on the other.

Non-Clinical Testing: Non-clinical testing demonstrated statistical equivalence between this device and the predicate.

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

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

SHIPPING ADDRESS
56 E. Bell Drive
Warsaw, IN 46582

OFFICE 219.267.6639 ■ FAX 219.267.8137 ■ E-MAIL biomet@biomet.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 2002

Ms. Sara B. Shultz
Regulatory Specialist
Biomet Orthopedics, Inc.
P.O. Box 587
Warsaw, IN 46581-0587

Re: K021828
Trade/Device Name: Small Hammer Toe Pin
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: June 3, 2002
Received: June 4, 2002

Dear Ms. Shultz:

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" (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,

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) : K021828

Device Name: Small Hammer Toe Pin

Indications For Use:

The Small Hammer Toe Pin is indicated for proximal interphalangeal (PIP) joint arthrodesis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

510(k) Number K021828