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JUL 17 2002

BIOMET
CORPORATE HEADQUARTERS

SUMMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor:
Biomet Orthopedics, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581 –0587

Contact Person:
Sara B. Shultz
Telephone: (574) 267-6639
Fax: (574) 372-1683

Proprietary Name: LactoSorb® Mini Interference Screw

Common or Usual Name: Arthrodesis screw

Classification Name: Fastener, Fixation, Biodegradable, Soft Tissue

Device Product Code: 87MAI

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
LactoSorb® Suture Anchor, K954443, Biomet, Inc.

Indications for Use: The LactoSorb® Mini Interference Screw is indicated for use in soft tissue to bone fixation in the hand, wrist, and shoulder in the presence of appropriate protection or immobilization.

Device Description: The LactoSorb® Mini Interference Screw is a resorbable screw that is preloaded on a driver much like those used with suture anchors. The screw is made out of LactoSorb®. The screw will be available in one size only.

Summary of Technologies: The device's technological characteristics (materials, design, sizing, indications) are similar to or identical to the predicate devices.

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

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

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Warsaw, IN 46581-0587

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56 E. Bell Drive
Warsaw, IN 46582

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219.267.6639

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219.267.8137

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2002

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

Re: K021254
Trade/Device Name: LactoSorb® Mini Interference Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: April 18, 2002
Received: April 19, 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 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): K021254

DEVICE NAME: LactoSorb® Mini Interference Screw

INDICATIONS FOR USE:

The LactoSorb® Mini Interference Screw is indicated for use in soft tissue to bone fixation in the hand, wrist, and shoulder in the presence of appropriate protection or immobilization.

for Mark N Milhous

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

510(k) Number K021254

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use yes (Per 21 CFR 801.109) OR Over-The-Counter-Use No (Optional Format 1-2-96)