K023718

DEC 0 4 2002

BIOMET

SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant or Sponsor:
Walter Lorenz Surgical, Inc
(A wholly owned subsidiary of Biomet, Inc.)
1520 Tradeport Drive
P.O. Box 18009
Jacksonville, FL 32229-8009
Establishment Registration Number: 1032347

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

Proprietary Name:
QuickSet Mimix™ Bone Void Filler

Common or Usual Name:
Calcium Phosphate Cement

Device Classification:
Implant, endosseous for bone filling and/or reconstruction (872.3640)

Device Product Code:
84GXP

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Mimix™ Bone Void Filler (K990290)

Indicated Use:
The QuickSet Mimix™ Bone Void Filler is a self-setting calcium phosphate cement indicated for the following craniofacial procedures:

1. Repair of neurosurgical burr holes
2. Craniotomy cuts and other cranial defects
3. Augmentation or restoration of bony contour in the craniofacial skeleton area no larger that 25 cm^2

Device Description: The QuickSet Mimix™ is packaged as separate, pre-measured powder and liquid components. The two components are designed to be mixed intraoperatively to produce a homogenous paste, which can then be applied to bone gaps or defects. Because of its apatitic nature, the material is highly biocompatible.

The powder component is a mixture of a ceramic calcium phosphate powder and sodium citrate dihydrate ($Na_3C_6H_5O_7 \bullet 2H_2O$). The liquid component is a solution comprised of anhydrous citric acid ($C_6H_8O_7$) and distilled water (H_2O).

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

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
574.267.6639 ■ FAX
574.267.8137 ■ E-MAIL
biomet@biomet.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 4 2002

Kacy Arnold, RN, MBA
Regulator Affairs Specialist
Biomet Manufacturing, Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587

Re: K023718
Trade Name: QuickSet Mimix™ Bone Void Filler
Regulation Number: 882.5300
Regulation Name: Methyl Methacrylate for Cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: October 31, 2002
Received: November 5, 2002

Dear Ms. Arnold:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 legallypredicate 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) : K023718

Device Name: QuickSet Mimix™ Bone Void Filler

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3. Augmentation or restoration of bony contour in the craniofacial skeleton area no larger that 25 cm^2

for Mark N Millerson

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

510(k) Number K023718

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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