K012569

p1/2

DEC 21 2001

BIOMET INC

CORPORATE HEADQUARTERS

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, Fla 32229-8009
Establishment Registration Number: 1032347

Contact Person:

Sara B. Shultz
Biomet Manufacturing, Corp.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46582
Phone: (219) 267-6639
FAX: (219) 372-1683

Proprietary Name:

Injectable Mimix™

Common Name:

Calcium Phosphate Cement

Classification Name:

Methyl Metacrylate for Cranioplasty (882.5300)
Prosthesis, Craniofacial (882.5330)

Device Product Code:

84GXP, 84JBA

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Craniofacial Calcium Phosphate Ceramic Bone Filler, K990290

Intended Use: The Injectable Mimix™ is a self-setting calcium phosphate cement intended for use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects as well as in the augmentation or restoration of bony contour in the craniofacial skeleton. The bone filler is not intended for percutaneous injection use.

Device Description: The Injectable Mimix™ is packaged as separate, pre-measured powder and liquid components. The two components are to be mixed intraoperatively and then inserted into a syringe style pipet that will be used to apply the filler to bone gaps or defects. The bone filler is indicated for the augmentation or restoration of bony contour in the craniofacial skeleton. The bone filler is not intended for percutaneous injection use.

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

SHIPPING ADDRESS
Airport Industrial Park
Warsaw, IN 46580

OFFICE
219.267.6639

FAX
219.267.8137

E-MAIL
biomet@biomet.com

BIOMET INC
CORPORATE HEADQUARTERS

The powder component is a mixture of a ceramic calcium phosphate powder and sodium citrate dihydrate ($Na_3C_6H_5O_7 \cdot 2H_2O$). 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.

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

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

SHIPPING ADDRESS
Airport Industrial Park
Warsaw, IN 46580

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

DEC 21 2001

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

Re: K012569
Trade Name: Injectable Mimix™
Regulation Number: 882.5300
Regulation Name: Methyl Methacrylate for Cranioplasty
Regulatory Class: Class II
Product Code: GXP
Dated: November 27, 2001
Received: November 30, 2001

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 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Barbara Zimmerman for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510 (k) Number (if known) : K012569

Device Name: Injectable Mimix™

Indications For Use:

The Injectable Mimix™ is a self-setting calcium phosphate cement intended for use in the repair of neurosurgical burr holes, craniotomy cuts and other cranial defects as well as in the augmentation or restoration of bony contour in the craniofacial skeleton.

The bone filler is not intended for percutaneous injection use.

(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)

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

00008

510(k) Number K012569