JAN 30 1998

K974309

SUMMARY OF SAFETY AND EFFECTIVENESS

The LactoSorb® Panels consist of sheets of LactoSorb® available in various sizes. The panels can be heated to malleable state and cut/shaped to conform to the bony anatomy. Heating is done using a sterile LactoSorb® Heat Pack.

The LactoSorb® Panels are used as fixation devices in the following procedures.

A. General Indication: trauma procedures of the midface or craniofacial skeleton
   Specific Indications:
   1. Comminuted fractures of the naso-ethmoidal infraorbital areas
   2. Comminuted fractures of the frontal sinus wall
   3. Pediatric midface or craniofacial trauma
   4. Orbital floor fractures
   5. Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones

B. General Indication: reconstructive procedures of the midface or craniofacial skeleton
   Specific Indications:
   1. Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma etc.)
   2. Tumor reconstruction in midface or craniofacial procedures
   3. Bone graft procedures in the midface or craniofacial skeleton
   4. Pediatric reconstructive procedures
   5. Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
   6. Craniotomy flap fixation

At the time of surgery, drill holes can be placed as needed to accept LactoSorb® screws and rivets. These devices are not for use in the mandible or other load bearing indications.

The LactoSorb® Panels are made of bioresorbable and biocompatible polymers that have been used in surgical procedures for years. LactoSorb® resorbable copolymer is a

synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic acid copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids which are then metabolized by the body. The LactoSorb® material has been found to be biocompatible in both soft tissue and bone tissue. The material retains its strength for at least 8 weeks and completely resorbs by 9-15 months.

The LactoSorb® Panels are used in a similar manner as the LactoSorb® mesh in the LactoSorb® Trauma Plating System as well as thin metal meshes and a variety of other devices. Biomechanical testing has proven that the LactoSorb® Panels will be as effective as the predicate devices in midface and craniofacial procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 30 1998

Ms. Mary Verstynen
Clinical Research Manager
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K974309
LactoSorb® Panels
Regulatory Class: II
Product Code: HRS
Dated: November 13, 1997
Received: November 17, 1997

Dear Ms. Verstynen:

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 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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" (21 CFR 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/dsmamain.html".

Sincerely yours,

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

Enclosure

510(k) Number (if known): K974309

Device Name: LactoSorb® Panels

Indications For Use:

A. General Indication: trauma procedures of the midface or craniofacial skeleton
Specific Indications:
1. comminuted fractures of the naso-ethmoidal infraobital areas
2. comminuted fractures of the frontal sinus wall
3. pediatric midface or craniofacial trauma
4. orbital floor fractures
5. trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones

B. General Indication: reconstructive procedures of the midface or craniofacial skeleton
Specific Indications:
1. Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma, etc.)
2. tumor reconstruction in midface or craniofacial procedures
3. bone graft procedures in the midface or craniofacial skeleton
4. pediatric reconstructive procedures
5. reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
6. craniotomy flap fixation

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K974309

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)