

K971870

Summary of Safety and Effectiveness

AUG 19 1997

The LactoSorb® Trauma Plating System is indicated for use in the following midface or craniofacial 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. LeFort (I,II,III) fractures
5. orbital floor fractures
6. fractures of the maxilla, zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones
7. 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. LeFort (I,II,III) osteotomies
3. tumor reconstruction in midface or craniofacial procedures
4. bone graft procedures in the midface or craniofacial skeleton
5. pediatric reconstructive procedures
6. reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
7. craniotomy flap fixation

This system is not designed for use in the mandible and/or full load bearing procedures.

The LactoSorb® plates/mesh/screws are made of bioresorbable and biocompatible polymer that have been used in surgical procedures for years. LactoSorb® resorbable copolymer is a synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic (PLA/PGA) acid copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids which are then metabolized by the body. The safety of PLA/PGA material has been well documented since the early 1970's when the FDA first approved the use of

resorbable PLA/PGA sutures. The exact same LactoSorb® material has been implanted in humans for over 10 years in the Poly Surgiclip® device manufactured by United States Surgical Corporation. The LactoSorb® material has been found to be biocompatible in both soft and hard bone tissue.

The effectiveness of this resorbable system was determined by mechanical testing and an FDA approved clinical study. The LactoSorb® system was found to provide adequate fixation in the craniomaxillofacial region with no device related complications reported. This system is as effective as similar metal micro fixation systems on the market. The devices completely resorb by 12 months IN VIVO eliminating the need for long-term removal.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 19 1997

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

Re: K971870
Trade Name: LactoSorb® Trauma Plating System
Regulatory Class: II
Product Codes: HRS and HWC
Dated: May 20, 1997
Received: May 21, 1997

Dear Ms. Verstynen:

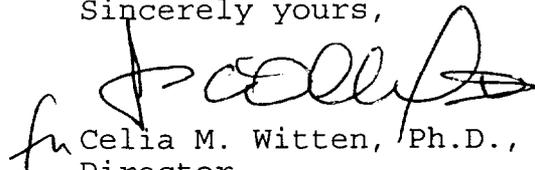
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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 pre-market 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) 594-4595. 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,



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

K971870

Page 1 of 1

510(k) Number (if known): _____

Device Name: LactoSorb Trauma Plating System

Indications For Use:

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. Lefort (I,II,III) fractures
5. Orbital floor fractures
6. Fractures of the maxilla, Zygoma, zygomatic arch, orbital rim, nasal, ethmoid, and lacrimal bones
7. Trauma of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones

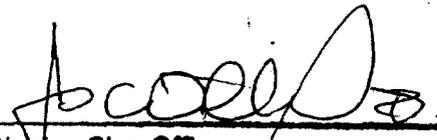
B. General Indication: reconstructive procedures of the midface or craniofacial skeleton

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1. Infant craniofacial surgery (i.e. craniosynostosis, congenital malformation, trauma etc.)
2. Lefort (I,II,III) osteotomies
3. Tumor reconstruction in midface or craniofacial procedures
4. Bone graft procedures in the midface or craniofacial skeleton
5. Pediatric reconstructive procedures
6. Reconstructive procedures of the craniofacial skeleton including: frontal, parietal, temporal, sphenoid, and occipital bones
7. 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 K-971870

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)