

DEC 20 1999

K 9 9 2 3 5 5

## 510 (k) Summary of Safety and Effectiveness

Submitter: Biomet Inc.  
Airport Industrial Park  
P.O. Box 587  
Warsaw, IN 46581-0587

Contact Person: Tracy Bickel

Product Code: HRS, HWC

Device Name: LactoSorb® Trauma Plating System

The LactoSorb® Trauma Plating System is intended for use in the following indications.

- 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

The devices are made of LactoSorb®, which is comprised of bioresorbable and biocompatible polymers that have been used in surgical procedures for years. The LactoSorb® resorbable copolymer is synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic acid copolymer degrades and resorbs *In Vivo* by hydrolysis into lactic and glycolic acids, which are then metabolized by the body. The LactoSorb® material has been found to be biocompatible in animal and clinical studies in both soft tissue and bone tissue. Additional designs have been added to the system which pose no new risks regarding safety and effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 20 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Tracy J. Bickel  
Regulatory Specialist  
Biomet Incorporated  
Airport Industrial Park  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K992355  
*LactoSorb* Trauma Plating System  
Regulatory Class: II  
Product Code: HRS, HWC  
Dated: December 2, 1999  
Received: December 6, 1999

Dear Ms. Bickel:

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.

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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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Neil R. P. Ogden" followed by a stylized flourish.

James E. Dillard III  
Acting Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K 9 9 2 3 5 5

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

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

DRG  
 (Division Sign-Off)  
 Division of General Restorative Devices  
 510(k) Number K992355

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

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