

3/23/99

K990291

1 of 1

## 510 (K) Summary of Safety and Effectiveness

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

Contact Person: Michelle L. McKinley

Product Code: 87HTY

Device Name: LactoSorb® Bone Pin

The LactoSorb® Bone Pin is indicated for use in the presence of appropriate immobilization in the following procedures:

1. correction of hallux valgus (bunion)
2. repair of metacarpal and phalangeal fusion and fractures

The LactoSorb® Bone Pin is made of bioresorbable and biocompatible polymers that have been used in surgical procedures for numerous years. LactoSorb® resorbable copolymer is a synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic acid (PLLA/PGA) copolymer degrades and resorbs IN VIVO by hydrolysis to lactic and glycolic acids, which are then metabolized by the body.

The effectiveness of the LactoSorb® Bone Pin was determined by In VITRO mechanical comparative testing to currently marketed resorbable pins. The tests showed that the LactoSorb® pins demonstrated adequate initial strength and retained at least 80% of that strength at 8 weeks. In the same test environment at eight weeks, the comparative pins exhibited little or no strength.

In summary, the LactoSorb® Bone Pin is safe and effective for metacarpel and phalangeal repair. Mechanical testing demonstrated the Lactosorb® Bone Pin to be as effective or better than comparative resorbable bone pins.

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MAR 23 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Michelle L. McKinley  
Regulatory Specialist  
Biomet, Inc.  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K990291  
Trade Name: LactoSorb® Bone Pin  
Regulatory Class: II  
Product Codes: HTY and MAI  
Dated: January 22, 1999  
Received: January 29, 1999

Dear Ms. McKinley:

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.

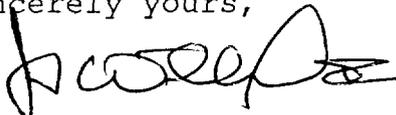
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Ms. Michelle L. McKinley

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,



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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): K990291

DEVICE NAME: LactoSorb® Bone Pin

INDICATIONS FOR USE:

The LactoSorb® Bone Pin is indicated for use in the presence of appropriate immobilization in the following procedures:

1. correction of hallux valgus (bunion)
2. repair of metacar pal and phalangeal fusion and fractures

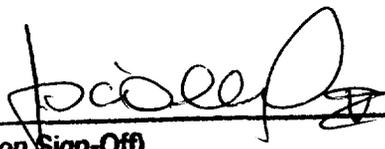
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X  
Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter-  
(Optional Format 1-2-96)

  
 \_\_\_\_\_  
 (Division Sign-Off)  
 Division of General Restorative Devices  
 510(k) Number K990291