

NOV 3 1998

510(k) Summary of Safety and Effectiveness

K981666

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

Contact Person: Mary L. Verstynen

Product Code: JEY

Device Name: 2.5 mm LactoSorb® Screws

The 2.5 mm LactoSorb® Screws are indicated for use as fixation in mandibular osteotomy procedures, including but not limited to:

1. sagittal split osteotomy
2. vertical ramus osteotomy
3. inferior border osteotomy
4. subapical osteotomy
5. genioplasty

The 2.5 mm LactoSorb® Screws are composed 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. In animal studies LactoSorb® has been found to be biocompatible in both soft tissue and bone tissue. LactoSorb® devices have been marketed for over two years for use in trauma and reconstructive procedures in the craniomaxillofacial skeleton and have been found to be both safe and effective.

The efficacy of the 2.5 mm LactoSorb® Screws have been demonstrated by biomechanical testing and clinical use. The screws maintain their strength for at least 6-8 weeks and completely resorb in approximately one year.

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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Mary L. Verstynen  
Biomet, Incorporated  
Airport Industrial Park  
Warsaw, Indiana 46581-0587

Re: K981666  
Trade Name: 2.5 mm LactoSorb® Screws  
Regulatory Class: II  
Product Code: DZL  
Dated: August 5, 1998  
Received: August 6, 1998

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 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). 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 requirements, 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

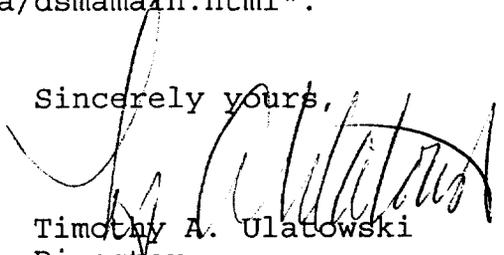
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4692. 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" (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/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control,  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): \_\_\_\_\_

DEVICE NAME: 2.5mm LactoSorb Screw

INDICATIONS FOR USE:

The 2.5mm LactoSorb Screws are indicated for use as fixation in mandibular osteotomy procedures, including but not limited to:

1. sagittal split osteotomy
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3. inferior border osteotomy
4. subapical osteotomy
5. genioplasty

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use   
(Per 21 CFR 801.109)

OR

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

Susan R. [Signature]  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K981666

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