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MICROFIXATION, INC.

1520 Tradeport Drive
Jacksonville, FL 32218
904-741-4400 fax 904-741-3912
Kim Reed, Regulatory Affairs Manager

SEP - 6 2007

510(k) Summary

Trade Name: Biomet Microfixation LactoSorb® Pectus Stabilizer

Classification and Common Name and Reference: Bone Plate CFR 21 888.3030

Product Code: HRS

Device Classification: Class II

Device Description: The LactoSorb® Pectus Stabilizer provides the surgeon with a means to secure the Pectus Support Bar to the chest wall. The Biomet Microfixation Pectus Bar is used to reposition bony structures (sternum, breastbone) by applying internal force outwardly eliminating the funnel shaped deformity. The LactoSorb® Pectus Stabilizer is a resorbable implant and does not require removal.

Intended Use: The Biomet Microfixation LactoSorb® Pectus Stabilizer is intended to be used with Lorenz Pectus Support Bars cleared via K972420 and K061384 for repairing Pectus Excavatum and other sternal deformities when additional stabilization is necessary.

Materials Lactosorb® (resorbable copolymer) – a polyester derivative of lactic and glycolic acids

Possible Adverse Effects:

1. Infection can lead to failure of the procedure.
2. Neurovascular injuries can occur due to surgical trauma.
3. Bending, fracture, loosening, rubbing and migration of the devices can occur as a result of excessive activity, trauma or load bearing.
4. Implantation of foreign materials can result in an inflammatory response or allergic reaction.
5. Sensitivity reactions or allergic reaction to the implant material.
6. Pain, discomfort, or abnormal sensation due to the presence of the device.
7. Surgical trauma; permanent or temporary nerve damage, permanent or temporary damage to heart, lungs, and other organs, body structures or tissues.
8. Skin irritation, infection, and pneumothorax.
9. Fracture, breakage, migration, or loosening of the implant.
10. Permanent injury or death.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain, which may not be related to the implant.

Substantial Equivalence: The Biomet Microfixation LactoSorb® Pectus Stabilizer is believed to be substantially equivalent in application and function to the Lorenz Pectus Stabilizer K981789, Lorenz Pectus Support Bar K972420 and Lorenz Pectus Support Bar System K061384.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biomet Microfixation, Inc.
% Ms. Kim Reed
Regulatory Affairs Manager
1520 Tradeport Drive
Jacksonville, FL 32218-2480

SEP - 6 2007

Re: K071577
Trade/Device Name: Biomet Microfixation LactoSorb® Pectus Stabilizer
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: August 10, 2007
Received: August 13, 2007

Dear Ms. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

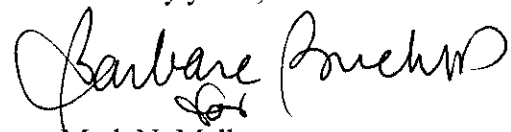
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: Biomet Microfixation LactoSorb® Pectus Stabilizer

Indications For Use:

The Biomet Microfixation LactoSorb® Pectus Stabilizer is intended to be used with Lorenz Pectus Support Bars cleared via K972420 and K061384 for repairing Pectus Excavatum and other sternal deformities when additional stabilization is necessary.

Prescription Use X AND/OR (Part 21 CFR 801 Subpart D)

Over-The-Counter Use No (21 CFR 801 Subpart C)

(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, and Neurological Devices

510(k) Number K071577