

510(k) Summary

Trade Name: Howmedica Leibinger Resorbable Fixation System

Common Name: Small Bone Plating System

Classification Name: Smooth or Threaded Metallic Bone Fixation Fastener 888.3040

The Howmedica Leibinger Resorbable Fixation system consists of a series of plates and mesh in varying configurations and lengths which are attached to the bone using screw fixation. The plates are available in two thicknesses (1.0mm and 1.5mm). The mesh is also available in two thicknesses (0.7mm and 1.2mm). Additionally, there are two screw diameters of 1.5mm and 2.0mm and a third emergency screw with a 2.5mm diameter. These plates and screws are intended for use in the fixation bones of the craniofacial and midfacial skeleton affected by trauma or for reconstruction. The plates and mesh can be contoured by heating. The system can be used in both adult and pediatric patients.

The substantial equivalence of this device is based on similarities in intended use, design and operational principles to the LactoSorb Trauma Plating System (Biomet) and the Luhr® Pan Fixation System (Howmedica). The material used in the manufacture of the Howmedica Leibinger Resorbable Fixation System is substantially equivalent to that used in the LactoSorb Device. Testing was performed to demonstrate an equivalence in performance to the LactoSorb Trauma Plating System (Walter Lorenz subsidiary of Biomet).

The basic operational principles for the use of small bone plating systems is similar for the Howmedica Leibinger Resorbable Fixation System, The LactoSorb Trauma Plating System and The Luhr® Pan Fixation System, that is to provide stabilization and fixation of small bones of the craniofacial and midfacial skeleton due to fracture or osteotomy. The method of site preparation, relative indications and contraindications is similar for the Howmedica System and the LactoSorb System.

For information contact: John Dichiaro
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OCT 16 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John F. Dichiaro
Director of Regulatory Affairs and Public Policy
Howmedica Inc.
Pfizer Medical Technology Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K982531
Trade Name: Howmedica Leibinger Resorbable
Fixation System
Regulatory Class: II
Product Codes: MAI, HWC, and HRS
Dated: July 17, 1998
Received: July 20, 1998

Dear Mr. Dichiaro:

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.

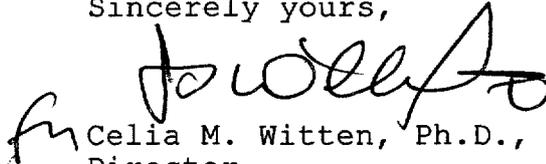
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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 (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

Indications for Use

510(k) Number (if known): Not Known

Device Name: Howmedica Leibinger Resorbable Fixation System

Indications for Use:

The Howmedica Leibinger Resorbable Fixation System is intended for use in the fixation of bones of the craniofacial and midfacial skeleton affected by trauma or for reconstruction. The system can be used in both adult and pediatric patients, but is not intended for use in the mandible and/or full load bearing procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)



(Division Sign-Off)
Division of General Restorative Devices

Number K982531