K 993061

NOV 19 1999

510(k) Summary of Safety and Effectiveness:
Stryker Leibinger Resorbable Fixation System

General Information

Proprietary Name:	Stryker Leibinger Resorbable Fixation System
Common Name:	Small Bone Plating System
Classification Name:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories
Classification Code:	87HRS
Submitter:	Stryker Leibinger 4100 E. Milham Ave. Kalamazoo, MI 49001
Submitter's Registration Number:	1811755
Manufacturer's Registration Number:	1811755
Contact Person:	Kristyn R. Kelley Project Engineer Quality Assurance and Regulatory Affairs 616-323-7700 x3814
Summary Preparation Date:	September 7, 1999

Equivalent Devices

The Stryker Leibinger Resorbable Fixation System is equivalent to the Howmedica Leibinger Resorbable Fixation System, Howmedica, K982531; the LactoSorb Trauma Plating System, Walter Lorenz, subsidiary of Biomet, K971870; the Macropore Protective Sheet (Protego System), Pacific Materials and Interfaces, K972913; and the BiosorbFX 1.5/2.0 Bioabsorbable Fixation System, Bionx Implants, Inc., K982139.

Device Description

The Stryker Leibinger Resorbable Fixation System is a modification of the Howmedica Leibinger Resorbable Fixation System, K982531. This second generation of products includes plates and screws in various configurations. Plates include but are not limited to straight, curved, "X", "Y", zigzag, "L", box,

ladder, and panel designs in varying lengths which are attached to the bone using screw fixation. The plates have a thickness of 1.0mm. The system also contains a mesh which is available in a thickness of 0.7mm. Screws are available in 1.7 mm, 2.0 mm and 2.2 mm diameters and standard craniofacial lengths. The plates and mesh can be intraoperatively contoured by heating. The subject device is fabricated from a polylactide and polyglycolide terpolymer. Mechanical testing has shown that the Stryker Leibinger device is equivalent in strength to the Walter Lorenz LactoSorb device.

Intended Use

The Stryker 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.

Substantial Equivalence

The subject device is substantially equivalent to the above mentioned devices in material, design, operational principle and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 19 1999

Ms. Kristyn R. Kelley
Project Engineer
Quality Assurance and Regulatory Affairs
Stryker Leibinger
4100 East Milham Avenue
Kalamazoo, Michigan 49001

Re: K993061
Stryker Leibinger Resorbable Fixation System
Regulatory Class: II
Product Codes: MAI, HWC, and HRS
Dated: September 7, 1999
Received: September 13, 1999

Dear Ms. Kelley:

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.

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,

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): ~~not known~~ K993061

Device Name: Stryker Leibinger Resorbable Fixation System

Indications For Use:

The Stryker 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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993061

Prescription Use X OR Over-The- Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)