DEC 23 1998

K983529

510(k) Summary

Proprietary Name:	Micro Dynamic Mesh
Common Name:	Titanium Mesh
Classification Name& Reference:	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories (21 CFR 888.3030)
Regulatory Class:	Class II
Device Product Code:	HRS

For information contact: Vivian Kelly
Manager, Regulatory Affairs
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Phone: (201) 507-7830
Fax: (201) 507-6870

Date Prepared: October 7, 1998

The Leibinger® Micro Dynamic Mesh is a titanium mesh available in different shapes, thicknesses, and perforation patterns to treat a variety of clinical applications. The material can be cut with scissors for precision fit, is malleable for three-dimensional adaptations, and is perforated to permit fluid exchange. The mesh is attached to bone by screws. The titanium construction allows for radiological identification but produces negligible artifacts on CT or MRI.

Micro Dynamic Mesh is intended to stabilize fractures, grafts and elective osteotomies for the reconstruction of the bones of the craniomaxillofacial skeleton, and oral cavity (including the mandible and maxilla).

The substantial equivalence of this device is based on the equivalence in intended use, materials, design, and operational principles to the currently marketed predicate devices such as TiMesh™ System (TiMesh Inc. & Sofamor Danek USA), 1.5/2.0 Combination Titanium Osteosynthesis System (Walter Lorenz) and Osteomed's TRAM™ .

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1998

Ms. Vivian Kelly
Manager, Regulatory Affairs
Howmedica, Incorporated
359 Veterans Boulevard
Rutherford, New Jersey 07070

Re: K983528
Trade Name: Micro Dynamic Mesh
Regulatory Class: II
Product Code: JEY
Dated: October 7, 1998
Received: October 8, 1998

Dear Ms. Kelly:

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 (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 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

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" (21CFR 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

Indications for Use

510(k) Number (if known):

Device Name: Leibinger® Micro Dynamic Mesh

Indications for Use:

Micro Dynamic Mesh is intended to stabilize fractures, grafts and elective osteotomies for the reconstruction of the bones of the craniomaxillofacial skeleton, and the oral cavity(including the mandible and maxilla).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983528

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