JAN 29 1999

K983885

510(k) Summary

Proprietary Name:	Burr Hole Covers
Common Name:	Burr Hole Covers
Classification Name & Reference	Burr Hole Cover 882.5250
Regulatory Class:	II
Device Product Code:	NE (84) GXR

For information contact:

Joseph Volpe
Senior Regulatory Affairs Specialist
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
Telephone: (201) 507-6695
Fax: (201) 507-6870

Date prepared: October 29, 1998

Intended use: The Leibinger Burr Hole Covers are designed to be used with fixation screws to cover burr holes of various diameters in the craniofacial skeleton in order to provide good cosmetic results and protection of the underlying soft tissues and brain. This device can also be used to secure cranial bone flaps.

Description: The Burr Hole Cover has a segmented plate-like structure. These Burr Hole Covers are 0.5mm thick and are comprised of four different configurations.

Substantial equivalence:

The substantial equivalence of these components is based on an equivalence in the intended use, materials, design, and operational principles to other predicate devices used for covering burr holes such as the Wurzburg Titanium Mini Bone Plating System and the Lorenz 1.5mm Neuro Pack/Lorenz 2.0 FT Plates.

510(k) Summary

Proprietary Name:	Craniomaxillofacial Plates
Common Name:	Small Bone Plates
Classification Name & Reference	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories (21 CFR 888.3030)
Regulatory Class:	II
Device Product Code:	OR (87) HRS

For information contact:

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Date prepared: October 29, 1998

Intended use: The Leibinger Two and Four-Hole Straight Plates are intended for fixation of small bones, including the craniofacial skeleton and midface bones, the fixation of facial bones following elective osteotomies and internal fixation of fractures of the hand.

Description: The Titanium Two and Four-Hole Straight Plates are holed plates which are attached to bone using screw fixation. They are similar in design to the straight plates of the Wurzburg Titanium Mini Bone Plating System. These plates are 0.5mm thick.

Substantial equivalence:

The substantial equivalence of these components is based on an equivalence in the intended use, materials, design, and operational principles to other predicate devices used for fixation of small bones, craniofacial skeleton, midface bones and hand, such as the Titanium Rigid Fixation & Bone Grafting – TiMesh Inc., Wurzburg Titanium Mini Bone Plating System and the Luhr® Pan Fixation System.

510(k) Summary

Proprietary Name:	Craniomaxillofacial Plates
Common Name:	Small Bone Plates
Classification Name & Reference	Single/Multiple Component Metallic Bone Fixation Appliances and Accessories (21 CFR 888.3030)
Regulatory Class:	II
Device Product Code:	OR (87) HRS

For information contact:

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Date prepared: October 29, 1998

Intended use: The Leibinger Temporal Gap Plates are intended for use with patients requiring reconstruction of the cranial area, including the sub-temporal regions. These plates provide fixation and stabilization of cranial bone flaps.

Description: The Titanium Temporal Gap Plates are holed plates which are attached to bone using screw fixation. The configurations vary to accommodate the level of reconstruction required for the patient's anatomy.

Substantial equivalence:

The substantial equivalence of these components is based on an equivalence in the intended use, materials, design, and operational principles to other predicate devices used for patients requiring reconstruction of the cranial area, including the sub-temporal regions. These plates provide fixation and stabilization of cranial bone flaps; bone gaps and defects; and fractures such as the Lorenz 1.5mm Neuro Pack/Lorenz 2.0 FT Plates and the Wurzburg Titanium Mini Bone Plating System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1999

Mr. Joseph Volpe
Senior Regulatory Affairs Specialist
Howmedica, Incorporated
359 Veterans Boulevard
Rutherford, New Jersey 07070

Re: K983885
Trade Name: Burr Hole Covers, Craniomaxillofacial Plates
Regulatory Class: II
Product Code: JEY
Dated: October 30, 1998
Received: November 2, 1998

Dear Mr. Volpe:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (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,

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 Burr Hole Covers

Indications for Use:

The Covers are intended for use in patients requiring craniofacial reconstruction to cover burr holes of various diameters in the craniofacial skeleton in order to provide good cosmetic results and protection of the underlying soft tissues and brain. This device can also be used to secure cranial bone flaps.

(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)

Susan Runo

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983885

Indications for Use

510(k) Number (if known):

Device Name: Leibinger Two and Four-Hole Straight Plates

Indications for Use:

The Plates are intended for use in patients requiring craniofacial fixation of small bones, craniofacial skeleton, midface bones and hand. These plates provide structure and support following elective osteotomies and internal fixation of fractures of the hand.

(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 ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983885

Indications for Use

510(k) Number (if known):

Device Name: Leibinger Temporal Gap Plates

Indications for Use:

The Plates are intended for use in patients requiring reconstruction of the cranial area, including the sub-temporal regions. These plates provide fixation and stabilization of cranial bone flaps.

(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)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K983883