K973982

510(k) Summary

JAN 12 1998

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

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

The Orbital Reconstruction Plates are a series of plates made from titanium with different configurations and thicknesses. The configurations vary to accommodate the level of reconstruction required or the patient's anatomy. The difference in thickness provides the necessary support for the internal orbit based on the type and extent of reconstruction required. The screws used with plates were previously cleared under various premarket notifications.

The plates are intended for use in patients requiring craniofacial reconstruction of the internal orbit. These plates provide structure and support to the orbital walls and/or floor when anatomical reconstruction of the internal orbit is necessary.

The substantial equivalence of these components is based on an equivalence in intended use, materials, design, and operational principles to other predicate devices used for orbital reconstruction plates such TiMesh's Titanium Mesh Tilghman Orbit Liner and Synthes' Universal Orbital Floor Plate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 1998

Ms. Vivian Kelly
Manager, Regulatory Affairs
Howmedica Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

Re: K973982
Trade Name: Orbital Reconstruction Plates
Regulatory Class: II
Product Code: HRS
Dated: October 16, 1997
Received: October 20, 1997

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 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,

for 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): K973982

Device Name: Orbital Reconstruction Plates

Indications for Use:

The plates are intended for use in patients requiring craniofacial reconstruction of the internal orbit. These plates provide structure and support to the orbit walls and/or floor when anatomical reconstruction of the internal orbit is necessary.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973982