



APR 11 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Kristyn R. Waski
Product Engineer--Special Projects
Howmedica Leibinger, Incorporated
14540 Beltwood Parkway East
Dallas, Texas 75244

Re: K970911
Trade Name: Lee Plate
Regulatory Class: II
Product Code: JEY
Dated: March 10, 1997
Received: March 12, 1997

Dear Ms. Waski:

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.

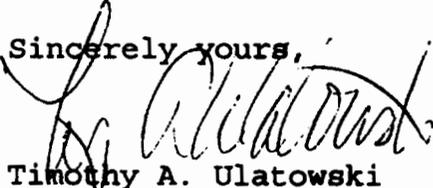
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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) 594-4618. 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 at (301) 443-6597.

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



510(k) Number (if known): _____

Device Name: Lee Plate

Indications for Use:

The Lee Plate is intended for use in internal fixation of corrective osteotomies to the symphysis region of the mandible (genioplasty procedures). The basic operational principle is to provide fixation/stabilization of an anterior mandibular bone segment that is freed during a corrective osteotomy procedure.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *Suzer Riviere*
Division of Dental, Infection Control,
and General Hospital Services
510(k) Number *K978911*

Prescription Use _____

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)

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1K970911

510(k) Summary

APR 11 1997

Device Proprietary Name: Lee Plate
Device Common Name: Small Bone Plate
Classification Name: Bone Plate 872.4760
Name of Submitter: Howmedica Leibinger Inc.
Contact Person: Kristyn Waski
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Date Prepared: March 10, 1997

Summary:

This submission describes a bone plate intended for use in internal fixation of corrective osteotomies to the symphysis region of the mandible (genioplasty procedures). It is designed to provide fixation to an advanced anterior mandibular bone segment. Screw holes allow for attachment to the anterior mandible and the osteotomized segment. 1.7 mm and 2.0 mm diameter screws are used to attach the plate to bone.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Profil-O-Plastic Chinplate [K862534 Paulus Titanium Mini Bone Plates and Screws]. Both plates are intended for use in the fixation of corrective mandibular osteotomies. Both plates are manufactured from commercially pure titanium. Both the Lee Plate and the Profil-O-Plastic Plates are contoured plates with screw holes to allow for attachment to mandibular bone. The operational principle and indications and contraindications are equivalent for both of these devices.