K031708

NOV - 3 2003

510(k) Summary

Device Proprietary Name:	OsteoMed Maxillary / LeFort III Distraction System
Device Common Name:	Intraoral Distractor
Classification Name:	MQN, External Mandibular Fixator and/or Distractor
Name of Submitter:	OsteoMed L. P. 3885 Arapaho Road Addison, Texas 75001 Phone: (972) 677-4600 Fax: (972) 677-6401
Contact Person:	Dawn T. Holdeman
Date Prepared:	May 27, 2003

Summary:

This submission describes the OsteoMed Maxillary / LeFort III Distraction System intended for use in the treatment of cranial or midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as, syndromic craniosynostosis, midfacial retrusion, hemifacial microsomia, and micrognathia. The OsteoMed Maxillary / Lefort III Distraction device is intended to provide temporary stabilization and gradual lengthening of the cranial or midfacial bones. This device is intended to be removed after consolidation. The OsteoMed Maxillary / LeFort III Distraction System is intended for single patient use only.

The OsteoMed Maxillary / LeFort III Distraction System is a distraction osteogenesis system consisting of distractor frame, bone plates, threaded rods, and an activation instrument. The plates attach to bone using bone screws and then gradually distract the osteotomized segment via activation of the threaded rod with the activation instrument.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Howmedica Leibinger Cohen Distractor (K972154)and the Lorenz Maxilla Distraction System (K982604).

Due to the similarity of materials and design to predicate devices, OsteoMed believes that the OsteoMed Maxillary / LeFort III Distraction System does not raise any new safety or effectiveness issues.

OsteoMed L.P.
3885 Arapaho Road
Addison, Texas 75001
(972) 677-4600 FAX: (972) 677-4601
Customer Service: (800) 456-7779

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 3 2003

OsteoMed L.P.
Ms. Dawn T. Holderman
Regulatory Affairs and Document Control
3885 Arapaho Road
Addison, Texas 75001

Re: K031708
Trade/Device Name: Osteomed Maxillary/Lefot III Distraction System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: September 26, 2003
Received: September 29, 2003

Dear Ms. Holderman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

OsteoMed "Indications for Use" Submission

510(k) Number: K031708

Device Name:	Osteomed Maxillary / LeFort III Distraction System
Indication for Use:	Intended for use in the treatment of cranial or midface conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as, syndromic craniosynostosis, midfacial retrusion, hemifacial microsomia, and micrognathia. The OsteoMed Maxillary / LeFort III Distraction device is intended to provide temporary stabilization and gradual lengthening of the cranial or midfacial bones. The OsteoMed Maxillary / LeFort III Distraction System is intended for single patient use only.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 810.109)

Over-The Counter-Use _____ (Optical Format 1-)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K031708