K 063792

OSTEOMED

510(k) Summary

MAR 0 2 2007

Device Proprietary Name:	OsteoMed External Mandibular Distraction System
Device Common Name:	External Distraction System
Classification Name:	MQN, External Mandibular Fixation and/or Distractor
Sponsor:	OsteoMed L. P. 3885 Arapaho Road Addison, Texas 75001 Phone: (972) 677-4600 Fax: (972) 677-4601
Contact Person:	Piedad Peña
Date Prepared:	February 14, 2007

Summary:

This submission describes the OsteoMed External Mandibular Distraction System, which is a family of external distraction osteogenesis devices for bone elongation for the correction of congenital deficiencies, mandibular hypoplasia or post traumatic defects of the mandible that require gradual distraction. This system is intended for use in either adults or pediatric patients. The OsteoMed External Mandibular Distraction System is intended for single patient use only.

The OsteoMed External Mandibular Distraction System is comprised of interchangeable distraction rods that connect to a posterior and anterior pin clamp, and/or the middle link. The anterior pin clamp can accommodate variations in pin placement. The pin clamps will accept 1.6 mm to 3.2 mm pins and lock to the pins via screws. The interchangeable distraction rods are available in various lengths for distraction up to 70 mm. The distraction rods are activated by a hex driver.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the KLS-Martin 3DX External Distraction System (K034027), the KLS-Martin LP, MOD Line of Molina Distractors 51-600 Series (K994154), Synthes (USA) External Multi Vector Mandible Distractor (K981362), and Lorenz External Mandibular Distractor (K992873).

Due to the similarity of materials and design to both pre-enactment and post-enactment devices, OsteoMed believes that the OsteoMed External Mandibular Distraction System, which includes adult and pediatric patients, does not raise any new safety or effectiveness issues.

OsteoMed L.P.
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 2 2007

Ms. Piedad Peña
Regulatory Affairs Associate
OsteoMed L.P.
3885 Arapaho Road
Addison, Texas 75001

Re: K063792
Trade/Device Name: OsteoMed External Mandibular Distraction System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: December 14, 2006
Received: December 22, 2006

Dear Ms. Pena:

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 (240) 276-0115. 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/industry/support/index.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

K063792

Indications for Use

510(k) Number (if known): _____

Device Name: OsteoMed External Mandibular Distraction System

Indications for Use:

The OsteoMed External Mandibular Distraction System, which is a family of external distraction osteogenesis devices for bone elongation for the correction of congenital deficiencies, mandibular hypoplasia or post traumatic defects of the mandible that require gradual distraction.

The OsteoMed External Mandibular Distraction System is intended for use in either adults or pediatric patients.

The OsteoMed External Mandibular Distraction System is intended for single patient use only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

Susan Runner

Division of General Hospital, Infection Control, Dental Devices

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