AUG 1 4 2002

K013618

OSTEOMED CORPORATION

510(k) Summary

Device Proprietary Name:	OsteoMed Intraoral Mandibular Distraction System
Device Common Name:	Intraoral Distractor
Classification Name:	MQN, External Mandibular Fixator and/or Distractor
Name of Submitter:	OsteoMed Corporation 3750 Realty Road Addison, Texas 75001 Phone: (972) 241-3401 Fax: (972) 241-3507
Contact Person:	Dawn T. Holdeman
Date Prepared:	October 31, 2001

Summary:

This submission describes the OsteoMed Intraoral Mandibular Distraction System indicated for use as a mandibular bone lengthener for patients diagnosed with conditions where treatment includes mandibular distraction osteogenesis. These conditions may include diagnoses such as mandibular micrognathia or hemifacial microsomia. The OsteoMed Intraoral Mandibular Distraction System is intended for single patient use only.

The OsteoMed Intraoral Mandibular Distraction System is a subcutaneous bone distractor. It features various curved and straight bars activated with a threaded wire that has screw holes that are fixed to bone via 1.6mm/2.0mm bone screws. The distractor is available in two sizes and in right and left versions. The threaded wire is activated by a hex driver and is capable of distraction lengths of up to 35mm.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the OsteoMed Intraoral Distraction System (K990944), Leibinger Vazquez-Diner Intraoral Distraction Device (K964649) and the Howmedica Guerrero-Bell Distractor (K972166).

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

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2002

Ms. Dawn T. Holdeman
Regulatory Affairs & Document Control
OsteoMed Corporation
3750 Realty Road
Addison, Texas 75001-4311

Re: K013618
Trade/Device Name: Intraoral Mandibular Distraction System
Regulation Number: Bone Plate
Regulation Name: 872.4760
Regulatory Class: II
Product Code: MQN
Dated: June 4, 2002
Received: June 5, 2002

Dear Mr. Holdeman:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594- 4613. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Patricia Cucuzzo/for

Timothy A. Ulatowski
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: K013618

Device Name:	Osteomed Intraoral Mandibular Distraction System
Indication for Use:	Indicated for use as a mandibular bone lengthener for patients diagnosed with conditions where treatment includes mandibular distraction osteogenesis. These conditions may include diagnoses such as mandibular micrognathia or hemifacial microsomia. The OsteoMed Intraoral Mandibular Distraction System is intended for single patient use only.

Susan Runyan

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

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