JUN 16 1999

K990944

OSTEOMED CORPORATION

510(k) Summary

Device Proprietary Name:	OsteoMed Intraoral 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:	March 19, 1999

specialized orthopaedic products

craniofacial reconstruction products

new product development

Summary:

This submission describes the OsteoMed Intraoral 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 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 bone screws. The distractor is available in right and left versions; The threaded wire is activated by a hex driver and is capable of distraction lengths of up to 25mm.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the 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 Distraction System does not raise any new safety or effectiveness issues.

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Dallas, Texas 75244
(972) 241-3401 FAX: (972) 241-3507
Customer Service: (800) 456-7779

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 16 1999

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

Re: K990944
Trade Name: OsteoMed Intraoral Distraction System
Regulatory Class: II
Product Code: MQN
Dated: March 19, 1999
Received: March 22, 1999

Dear Ms. Holdeman:

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.

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) 594-4692. 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,

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): K990944

Device Name: Osteomed Intraoral Distraction System

Indications 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runyon

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K990944

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

(Optional Format 1-2-96)