MAR 2 3 2004

510(K) SUMMARY
(as required by 807.92(c))
K034045

Submitter of 510(k): **Oral Osteodistraction, L.P.**
600 W. Lake Cook Rd., Suite 150
Buffalo Grove, IL 60089

Phone: **847-215-7554**
Fax: **847-215-7563**

Contact Person: **Yan Razdolsky**

Date of Summary: March 14, 2004

Trade Name: Oral Osteodistraction Distraction Rod Appliances (Rod 4)

Classification Name: External Maxillary Fixator and/or Distractor - MQN

Predicate Device:

KLS Martin Rigid External Distractor K972047
Oral Osteodistraction Rod Appliances (Rod 1,2,3) K014001

Intended Use:

The Rod-4 Distraction device is utilized for the purpose of maxillary and midface Osteodistraction in the reconstruction of patients with congenital and acquired craniofacial anomalies, narrow and underdeveloped maxilla.

Device Description:

The device consists of two to four preformed stainless steel crowns, which are cemented over maxillary first permanent molars and first permanent bicuspids. Stainless steel crowns have male and female precision attachments welded to them prior to cementation. Three Leone hyraax screws are also welded to the above-described attachments (two on the buccal and one on the palatal surfaces). The device is activated by a screwdriver, which is inserted in to the screwdriver slot of the hyraax screw and then rotated. The device is predominately - tooth bone, with KILS bone plates attached to the bone. Surgical mini screws are required to secure bone plates to the bone. Removal of the device requires removal of mini screws and removal of the crows.

Comparison Chart

Rod 4 is essentially the same as Rods 1-3 except for the location of axis change.

	Oral Osteodistraction ROD 1, 2, 3 – K014001	Oral Osteodistraction Rod 4	KLS Martin - K972047
Material	Stainless Steel 304	Stainless Steel 304	T1-6AL-4V Titanium Alloy
Facial Skeleton/Pins	Stainless Steel 301	Stainless Steel 301	T1-6AL-4V Titanium Alloy
Distraction Rate	.5mm/day first 2 days then 1mm/day after that	Same	1mm/day
Fixed to Patient Bone	Screws	Screws	Screws
Completed Distraction	Geared Rod	Geared Rod	Geared Rod
Distraction Activation	Hex Key	Same	Same
Facial Bone Distractor	Intraoral	Intraoral	Intraoral and External
Intended Use	Mandible Distraction	Maxillary	Maxillary
Device Placement	Subcutaneous	Same	Same
User	Craniofacial Surgeon	Same	Same

Additional Comparison

	Oral Osteodistraction ROD 1, 2, 3 – K014001	Oral Osteodistraction Rod 4	KLS Martin - K972047
Site of Distraction	Tooth-borne	Tooth-borne	Tooth- borne and External
Latency Period	5-7 Days	Same	Same
Distraction Period	7-14 Days	Same	Same
Consolidation Period	8-12 Weeks	Same	Same
Surgical Technique	Osteotomy	Same	Same
Placement	Internal	Internal	External

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2004

Oral Osteodistraction, L.P.
C/O Mr. Arthur Ward
RMS, Incorporated
962 Allegro Lane
Apollo Beach, Florida 33572

Re: K034045
Trade/Device Name: Oral Osteodistraction Distraction Rod Appliance (Rod 4)
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: December 1, 2003
Received: December 29, 2003

Dear Mr. Ward:

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.

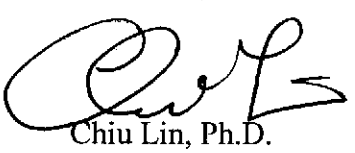
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-5613. 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

510(k) Number (if known): K034045

Device Name: Oral Osteodistraction Distraction Rod Appliance (Rod 4)

Indications For Use:

The Rod-4 Distraction device is utilized for the purpose of maxillary and midface Osteodistraction in the reconstruction of patients with congenital and acquired craniofacial anomalies, narrow and underdeveloped maxilla.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

510(k) Number: K034045