K042278

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

JAN 2 8 2005

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: July 1, 2004

Trade/Proprietary Name: Oral Osteodistraction Distraction Rod Appliance (ROD 5)

Classification Name: External Mandibular Fixator and/or Distractor

Product Code: MQN

Predicate Device: KLS-Martin Track Distractor K002152

Intended Use:

The Rod-5 Distraction device is intended for use in patients with bone loss due to periodontal disease, trauma or post tumor resection, Ankylosed teeth, or Atrophic boney areas inadequate for implant placements or restorative procedures which need to increase in bone mass and height by means of distraction osteogenesis.

Device Description:

The device consists of two bondable attachments and a horizontal rod that spans the distraction site. the rod is supported by these attachments which are bonded to the teeth and has holes for engagement of distraction wire. The spring washers and detents allow for activation of the device during distraction and provide a self-locking mechanism to prevent deactivation of the device. The device is activated by a screwdriver, which is inserted in to the screwdriver slot, pushed against the washer to disengage the detent, and then rotated. The device is predominately – tooth bone, with only a fixation wire attached to the bone; no screws are required. Removal of the device requires only cutting the fixation wire. The wire can then be pulled through the bone and soft tissue without the need for an incision.

Comparison Chart

	Oral Osteodistraction ROD – 5	KLS Martin Track Distractor – K002152
Material	Polyurethane and Stainless Steel	T1-6AL-4V Titanium Alloy
Distraction Rate	1.0 mm/day	Same
Distraction Mechanism	Rod with holes for distraction wire (.025") attached through pt. bone	Threaded rod with attached titanium plates fixed to one with titanium screws
Distraction Activation	Screwdriver	Same
Site of Distraction	Tooth-borne, bone borne (wire only)	Bone borne
Target Use	Cranio/Facial surgeons	Same
Latency Period	3-7 Days	5-7 Days
Distraction Period	7-14 Days	Same
Retention Period	3-6 Weeks	Same
Intended Use	Maxillo Mandibular deficiencies	Same
Surgical Technique	Osteotomy	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 8 2005

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

Re: K042278
Trade/Device Name: Oral Osteodistraction Distraction Rod Appliance (ROD 5)
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: December 22, 2004
Received: January 21, 2005

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.

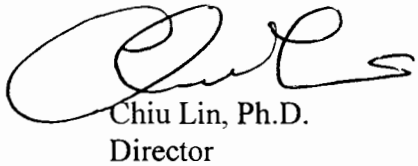
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) Number (if known): K042278

Device Name: Oral Osteodistraction Distraction Rod Appliance (ROD 5)

Indications for Use:

The Rod-5 Distraction device is intended for use in patients with bone loss due to periodontal disease, trauma or post tumor resection, Ankylosed teeth, or Atrophic boney areas inadequate for implant placements or restorative procedures which need to increase in bone mass and height by means of distraction osteogenesis.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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