K014001

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

FEB 0 4 2003

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

Phone: **847-215-7554**
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Contact Person: **Yan Razdolsky**

Date of Summary: October 10, 2001

Trade Name: Oral Osteodistraction Distraction Rod Appliances (Rod 1, Rod 2 and Rod 3)

Classification Name: External Mandibular Fixator and/or Distractor

Predicate Device:

KLS-Martin	**Intraoral Distractor**	**K973275**
Synthes	**Mandibular Distractor**	**K962272**

Intended Use:

The Oral Osteodistraction Distraction Rod Appliances is intended to be used in the mandible for conditions such as mandibular deficiency or post-traumatic effects of the mandible, where gradual bone distraction is required.

Device Description:

Distraction Osteogenesis Rod Appliances are used for mandibular bone distraction.

The major components include:

1. KLS Martin bone plates and screws.
2. Ormco Stainless steel crowns, Herbst Rods.
3. Leone expansion screws.

Comparison Chart

	Oral Osteogenesis	**KLS-Martin**	**Synthes**
Material	Stainless Steel 304	TI – 6AL4V Titanium Alloy	Surgical Stainless Steal
Facial Skeleton/Pins	Stainless Steel 301	TI – 6AL4V Titanium Alloy	Surgical Stainless Steal
Distraction Rate	.5mm/day first 2 days then 1mm/day after that	1mm/day	1mm/day
Fixed to Patient Bone	Screws	Screws	Screws
Completed Distraction	Geared Rod	Geared Rod	Geared Rod
Distraction Activation	Hex Key	Same	Screwdriver External
Facial Bone Distractor	Intraoral	Intraoral	Internal
Intended Use	Mandible Distraction	Same	Same
Device Placement	Subcutaneous	Same	Same
User	Craniofacial Surgeon	Same	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 4 2003

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

Re: K014001
Trade/Device Name: Oral Osteodistraction Distraction Rod Appliances
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: November 26, 2002
Received: December 9, 2002

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) 594-4613. 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,

Susan Runner

Susan Runner, DDS, MA
Interim 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): K014001

Device Name: Oral Osteodistraction Distraction Rod Appliances

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

(Optional Format 1-2-96)

Sharon Kunn

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

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