

K 973275

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

NOV 20 1997

Submitter of 510(k): Regulatory & Marketing Services, Inc. (RMS)
P.O. Box 1108
Elfers, FL 34680

Phone: 813-376-4154
Fax: 813-376-7186

Contact Person: Ed Ransom

Date of Summary: August 26, 1997

Trade Name: KLS-Martin Intraoral Distractor

Classification Name: Mandible Distractor

Predicate Device: Synthes Mandible Distractor K962272

**Device Description/
Comparison:** The KLS-Martin Intraoral Distractor is a subcutaneous bone distractor. It features two telescoping components activated by a jack screw, fixed to the bone via subcutaneous plates and secured with 1.5mm bone screws. A hex driver is used to activate the required distraction.

Intended Use: The KLS-Martin Intraoral Distractor 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ed Ransom
•President
KLS-Martin L.P.
C/O Regulatory & Marketing Services, Incorporated
3234 Ella Lane
New Port Richey, Florida 34655

NOV 20 1997

Re: K973275
Trade Name: KLS-Martin Intraoral Distractor
Regulatory Class: Unclassified
Product Code: MQN
Dated: August 26, 1997
Received: September 2, 1997

Dear Mr. Ransom:

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.

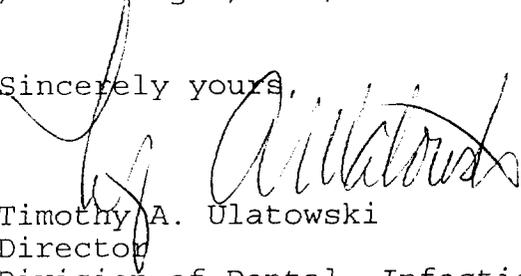
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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) 594-4618. 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): K973275

Device Name: KLS-Martin Intraoral Distractor

Indications For Use:

The KLS-Martin Intraoral Distractor 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. (Micrognathia, Hemifacial Microsomia, Congenital Craniofacial Syndromes)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) *Meredith Shyns*
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K973275

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use