FEB 15 2000 K994154

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

Submitter of 510(k):	Regulatory & Marketing Services, Inc. (RMS) 3234 Ella Lane New Port Richey, FL 34655 Phone: 727-376-4154 Fax: 727-376-7186
Contact Person:	Art Ward
Date of Summary:	December 2,1999
Trade Name:	MOD Line of Molina Distractors
Classification Name:	Plate, Bone
Predicate Device:	K945500 Molina Distractor Wells Johnson
Device Description/ Comparison:	The KLS-Martin Molina Distractor is a mandibular fixation device consisting of Uni-directional and Bi-directional distractors and pins for anchoring. The product is identical to the predicate device except for material which is a titanium alloy rather than stainless steel.
Intended Use:	The KLS-Martin Molina Distractors are external Distractors for bone elongation. It is used for the correction of asymmetric mandibular deficiencies and mandibular hypoplasia. The devices are external and are anchored to the mandible by external fixation pins.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 15 2000

KLS-Martin L.P.
c/o Mr. Arthur Ward
Regulatory & Marketing Sevices, Incorporated
3234 Ella Lane
New Port Richey, Florida 34655

Re: K994154
Trade Name: Mod Line of Molina Distractors, 51-600 Series
Regulatory Class: II
Product Code: JEY
Dated: December 2, 1999
Received: December 9, 1999

Dear Mr. Ward:

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): K994154

Device Name: KLS-Martin Molina Distractor

Indications For Use:

The KLS-Martin Molina Distractors are intended for use as external distractors for bone elongation. It is used for the correction of asymmetric mandibular deficiencies and mandibular hypoplasia. The devices are external and are anchored to the mandible by external pins.

(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)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K994154