FEB 27 2004

K034027

510(K) SUMMARY

Submitter:	KLS-Martin, L.P. 11239-1 St. Johns Industrial Parkway South Jacksonville, FL 32246 Phone: 904-641-7746 Fax: 904-641-7378
Contact Person:	Jennifer Damato Director RA/QA
Date of Summary:	December 19, 2003
Device Name:	KLS Martin 3DX External Distraction System
Trade Name:	3DX External Distraction System
Common Name:	External Distraction System
Classification Name and Number:	Plate, Bone (CFR 872.4760)
Regulatory Class:	Class II
Predicate Devices:	KLS Martin Molina Distractor (K994154) Howmedica Inc. Mandibular Bone Distractor II (K960297) Synthes External Multi Vector Mandible Distractor (K981362) Lorenz External Mandibular Distractor (K992873)
Intended Use:	The KLS-Martin 3DX External Distraction System is a bone stabilizer and lengthening device when congenital deficiencies, mandibular hypoplasia or post traumatic defects of the mandible require gradual bone lengthening, including bone transport.
Device Description:	The device is comprised of two (2) interchangeable distraction arms, a central body which allows angular adjustment of the arms and pin clamps. The pin

clamps will accept 2.0mm and 2.7mm Molina (K994154) pins. Bone stabilization can be achieved with carbon rods after distraction.

Technological Characteristics:

Similarities to Predicate

The KLS Martin 3DX External Distraction System is the next generation in development based upon the KLS Martin Molina Distractor (K994154). The KLS Martin 3DX External Distraction System is similar to the Howmedica Inc. Mandibular Bone Distractor II (K960297), Synthes External Multi Vector Mandible Distractor (K981362) and the Lorenz External Mandibular Distractor (K992873)

Substantial Equivalence:

The KLS Martin 3DX External Distraction System is substantially equivalent in application and function to the KLS Martin Molina Distractor (K994154), the Howmedica Inc. Mandibular Bone Distractor II (K960297), the Synthes External Multi Vector Mandible Distractor (K981362) and the Lorenz External Mandibular Distractor (K992873).

Substantial equivalence is based on comparison of performance, method of distraction, bone stabilization and clinical literature assessment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2004

Ms. Jennifer Damato
Director Regulatory Affairs Quality Assurance
KLS-Martin, L.P.
11239-1 Saint Johns Industrial
Parkway South
Jacksonville, Florida 32246

Re: K034027
Trade/Device Name: KLS Martin 3DX External Distraction System
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: December 19, 2003
Received: December 29, 2003

Dear Ms. Damato:

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.

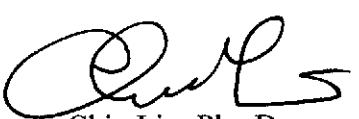
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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): K034027

Device Name: KLS Martin 3DX External Distraction System

Indications For Use:

The KLS Martin 3DX External Distraction System is a bone stabilizer and lengthening device when congenital deficiencies, mandibular hypoplasia or post traumatic defects of the mandible require gradual bone lengthening, including bone transport.

Prescription Use ✔ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

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

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