APR 18 2006

K060177

KLS martin L.P.

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:	12 January 2006
Device Name:	KLS Martin Rigid Fixation- Sterile
Trade Name:	Sterile Packaged Rigid Fixation
Common Name:	Bone Plate
Classification Name and Number:	Bone Plate (CFR 872.4760)
Regulatory Class:	II
Predicate Devices:	KLS-Martin Mandibular/Reconstruction System II (K032442) Resorb-X Resorbable Plating System (K011590) Centre-Drive Drill-Free Screw (K971297) Micro Osteosynthesis System (1.0) (K944561) KLS-Martin Micro Osteosythesis System (1.5mm) (K944565)
Device Description:	The KLS Martin Rigid Fixation - Sterile includes titanium plates of various shapes and thickness, titanium screws of various length and diameter, stainless steel twist drills of various length and diameter and stainless steel sonotrode tips that are provided in sterile packaging.

Intended Use:

The KLS Martin Rigid Fixation - Sterile is intended to provide KLS Martin's osteosynthesis products in sterile packaging. These products have been previously cleared for sale and providing them sterile does not change the already cleared intended use.

Technological Characteristics:

Similarities to Predicate

KLS Martin Rigid Fixation - Sterile is identical in manufacturing and design to the KLS-Martin Mandibular/Reconstruction System II (K032442), Centre-Drive Drill-Free Screw (K971297) Micro Osteosynthesis System (1.0) (K944561) and KLS-Martin Micro Osteosythesis System(1.5mm) (K944565).

Sterilization method of the KLS Martin Rigid Fixation - Sterile will be by gamma radiation which is the exact same process as cleared in Resorb-X Resorbable Plating System (K011590)

Differences to Predicate

KLS Martin Rigid Fixation - Sterile will be packaged sterile and will have different stock numbers from originally cleared stock numbers to identify the product as sterile.

Substantial Equivalence:

KLS Martin Rigid Fixation - Sterile are substantially equivalent to the KLS-Martin Mandibular/Reconstruction System II (K032442), Centre-Drive Drill-Free Screw (K971297) Micro Osteosynthesis System (1.0) (K944561) and KLS-Martin Micro Osteosythesis System(1.5mm) (K944565).

KLS Martin Rigid Fixation - Sterile are substantially equivalent to the Resorb-X Resorbable Plating System (K011590) in packaging and sterilization methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 18 2006

Ms. Jennifer Damato
KLS Martin, L.P.
11239-1 St. Johns Industrial Parkway South
Jacksonville, Florida 32246

Re: K060177
Trade/Device Name: KLS Martin Rigid Fixation - Sterile
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: January 12, 2006
Received: January 23, 2006

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 (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 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 continue 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 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (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): K060177

Device Name: KLS Martin Rigid Fixation - Sterile

Indications for Use: KLS-Martin Rigid Fixation - Sterile is intended to provide, in sterile packaging, osteosynthesis products with the following indications for use.

K051236: The RESORB-X® SF Sonotrode is only intended for use for insertion of the RESORB-X® SF pins.

K032442: The KLS Martin Mandibular/Reconstruction System II is intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.

K971297: The KLS Martin Centre-Drive Drill-Free screws are intended for use in rigid internal fixation of the oral-maxillo-cranio-facial bones. The bone screws are used to anchor plates which are contoured to fit the bony surface and stabilize the bone fragments. The addition of the self drilling feature is the only difference between the submitted device and the predicate device reference.

K944565: The KLS-Martin Micro Osteosynthesis System is used in oral-maxillo-cranio-facial surgery to stabilize fractured bone structures. The bone segments are attached to the plate with screws to prevent movement of the segments.

K944561: The KLS-Martin Micro Osteosynthesis System is used in oral-maxillo-cranio-facial surgery to stabilize fractured bone structures. The bone segments are attached to the plate with screws to prevent movement of the segments.

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

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