K032442

OCT 2 9 2003

KLS martin L.P.

P.O. Box 50249 • Jacksonville, FL 32250-0249
904-641-7746 or 1-800-625-1557 • Fax 904-641-7378
www.klsmartin.com

510(k) SUMMARY

Submitter of 510(k):

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

Summary Date:

27 June 2003

Device Name:

KLS Martin Mandibular / Reconstruction System II

Trade Name:

Mandibular / Reconstruction System II

Common Name:

Plate, Bone

Classification Name and Number:

Plate, Bone (CFR 872.4760)

Regulatory Class:

Class II

Predicate Devices:

Synthes Universal 2.4mm Locking Plate System (K961421)

Synthes 2.0 Locking Plate System (K974555)

KLS-Martin Mandibular / Reconstruction System (K950045)

KLS Mini Osteosynthesis System (K943347)

OSTEOMED 2.0 Locking Plates and Screws (K030448)

KLS-Martin Temporary Condylar Implant (K990667)

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Device Description:

KLS-Martin Mandibular Fracture / Reconstruction II includes several different designs of titanium plates and screws. New plates added to system are angled and pre-curved to follow the natural curves of the Mandible.

Changes to this fracture / reconstruction system are not functionally different and could typically be addressed with letter to file for predicate 510(k)s. This 510(k) ensures plates and screws listed have current 510(k)s.

Intended Use:

KLS Martin Mandibular / Reconstruction System II is intended for use in stabilization and fixation of Mandibular Fractures and Reconstruction.

Technological Characteristics:

Similarities to Predicate

Changes to this fracture / reconstruction system are not functionally different and could typically be addressed with letter to file for predicate 510(k)s. This 510(k) ensures plates and screws listed have current 510(k)s.

Plates and screws are similar to Synthes Universal 2.4mm Locking Plate System (K961421), Synthes 2.0 Locking Plate System (974555), KLS-Martin Mandibular / Reconstruction System (K950045), KLS Mini Osteosynthesis System (K943347), OSTEOMED 2.0 Locking Plates and Screws (K030448), and KLS-Martin Temporary Condylar Implant (K990667).

Screws are offered in diameter from 2.0mm to 3.2mm, lengths of 8mm through 22mm, and are available in standard or locking threads. Plates vary in thickness and are available as non-compression, compression, and threaded types.

Plates and screws are either commercially pure (CP) Titanium or Ti-6AL-4V Titanium Alloy.

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Plates and screw designs are of similar shape and size of competitive products for Mandibular Fracture and Reconstruction.

Differences to Predicate

New plates added to system are angled and pre-curved to follow the natural curves of the Mandible.

The new plates do not represent a major modification to system.

Substantial Equivalence:

The KLS-Martin Mandibular / Reconstructive System II is substantially equivalent in application and function to the Synthes Universal 2.4mm Locking Plate System (K961421), Synthes 2.0 Locking Plate System (K974555), KLS-Martin Mandibular / Reconstruction System (K950045), KLS Mini Osteosynthesis System (K943347), OSTEOMED 2.0 Locking Plates and Screws (K030448), and KLS-Martin Temporary Condylar Implant (K990667).

Substantial equivalence is based on comparison of performance, method of rigid bone fixation and similarity of materials. The new plates do not represent a major modification to system.

Intended use of the KLS-Martin Mandibular / Reconstructive System II is similar to the Synthes Universal 2.4mm Locking Plate System (K961421), Synthes 2.0 Locking Plate System (K974555), KLS-Martin Mandibular / Reconstruction System (K950045), KLS Mini Osteosynthesis System (K943347), OSTEOMED 2.0 Locking Plates and Screws (K030448), the function of this system being to affix Mandibular bony fragments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 9 2003

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

Re: K032442
Trade/Device Name: KLS Martin Mandibular / Reconstruction System II
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: August 4, 2003
Received: August 8, 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.

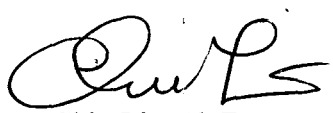
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

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Indications for Use

510(k) Number (if known): K032442

Device Name: KLS Martin Mandibular / Reconstruction System II

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

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IS NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulvey for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices
510(k) Number: K032442

Prescription Use X OR Over-The-Counter Use
(Per 21 CFR 801-109)

(Optional Format 1-2-96)