MAY 1 3 2004

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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

March 5th, 2004

Device Name:

KLS Martin Hand Plating System

Trade Name:

Hand Plating System

Common Name:

Small Bone Plating System

Classification Name and Number:

Single/Multiple Component Metallic Bone Fixation Appliances and Accessories (CFR 888.3030)

Regulatory Class:

Class II

Predicate Devices:

Profyle™ Titanium Hand and Small Fragment System (K961497)

Lorenz Small Fragment System (K992961)

Normed Extremity Titanium Hand and Small Fragment System (K011118)

KLS Martin Mandibular Fracture/Reconstruction System II (K032442)

KLS-Martin Micro Osteosythesis System(1.5mm) (K944565)

Micro Osteosynthesis System (1.0mm)(K944561)

Device Description:

The KLS Martin Hand Plating System consists of plates of various lengths and thickness from 0.6mm to 3.0mm and screws of various lengths having a diameter of 1.0mm to 2.7mm.

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Intended Use:

The KLS Martin Hand Plating System is used for stabilization and fixation of fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, wrist, fingers, feet, ankles and toes.

Technological Characteristics:

Similarities to Predicate

Plates and screws of the KLS Martin Hand Plating System are similar to the Profyle™ Titanium Hand and Small Fragment System (K961497), Lorenz Small Fragment System (K992961), Normed Extremity Titanium Hand and Small Fragment System (K011118).

Plates and screws of the KLS Martin Hand Plating System are identical in materials and manufacturing processes to the KLS Martin Mandibular Fracture/Reconstruction System II (K032442), KLS-Martin Micro Osteosythesis System(1.5mm) (K944565) and the Micro Osteosynthesis System (1.0mm)(K944561).

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

Differences to Predicate

The KLS Martin Hand Plating System contains plates that are pre-curved to follow the natural curves of the bones of the hand and feet. These plates are different in shape to the KLS Martin Mandibular Fracture/Reconstruction System II (K032442) KLS-Martin Micro Osteosythesis System(1.5mm) (K944565) and the Micro Osteosynthesis System (1.0mm)(K944561) but are of identical materials and manufacturing procedures.

The KLS Martin Hand Plating System contains 1.5mm screws that have a head that has a larger diameter than the KLS-Martin Micro Osteosythesis System(1.5mm) (K944565) but are of identical materials and manufacturing procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 3 2004

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

Re: K040598
Trade/Device Name: KLS Martin Hand Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: March 05, 2004
Received: March 08, 2004

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.

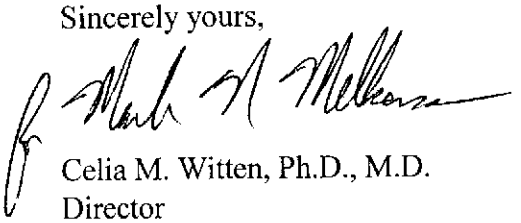
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4659. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040598

Device Name: KLS Martin Hand Plating System

Indications For Use: The KLS Martin Hand Plating System is used for stabilization and fixation of fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, wrist, fingers, feet, ankles and toes.

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)

for Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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