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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:

27 July 2004

Device Name:

KLS-Martin Hand Distractor

Trade Name:

KLS-Martin Hand Distractor

Common Name:

Internal Distractor

Classification Name and Number:

Smooth or threaded metallic bone fixation fastener (CFR 888.3040)

Regulatory Class:

Class II

Predicate Devices:

KLS-Martin Intraoral Distractor (K973275)

KLS-Martin Intra-Oral Mandibular Distractor (K983515)

Hoffmann II Compact External Fixation System (K971755)

Acumed Stableloc II External Fixation System (K965029)

Intended Use:

The KLS Martin Hand Distractor is designed to be used in finger reconstruction of the thumb or the metacarpal bones I - IV after amputation or malformation.

Device Description:

The KLS Martin Hand Distractor is a subcutaneous bone distractor. It features two telescoping components activated by a jackscrew, fixed to the bone with plates and secured with titanium bone screws.

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Technological Characteristics:

Similarities to Predicate

The KLS-Martin Hand Distractor is a subcutaneous bone distractor similar in technology and design to the KLS-Martin Intra-Oral Mandibular Distractor (K983515) and KLS-Martin Intra-Oral Distractor (K973275).

The KLS-Martin Hand Distractor is similar in intended use as the Hoffmann II Compact External Fixation System (K971755) Acumed Stableloc II External Fixation System (K965029)

Differences to Predicate

The KLS-Martin Intra-Oral Mandibular Distractor (K983515) and KLS-Martin Intra-Oral Distractor (K973275) are designed for the mandible and the KLS-Martin Hand Distractor is designed for distraction of the thumb and metacarpal bones.

The Hoffmann II Compact External Fixation System (K971755) Acumed Stableloc II External Fixation System (K965029) are external devices and the KLS-Martin Hand Distractor is a subcutaneous bone distractor.

Substantial Equivalence:

The KLS-Martin Hand Distractor is substantially equivalent in design and manufacturing to the KLS-Martin Intra-Oral Mandibular Distractor (K983515) and KLS-Martin Intra-Oral Distractor (K973275) and substantially equivalent in intended use as the Hoffmann II Compact External Fixation System (K971755) Acumed Stableloc II External Fixation System (K965029).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 5 2004

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

Re: K042066
Trade/Device Name: KLS Martin Hand Distractor
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliance and accessories
Regulatory Class: II
Product Code: JEC
Dated: July 27, 2004
Received: August 2, 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) 594-4692. 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):

Device Name: KLS Martin Hand Distractor

Indications For Use:

The KLS Martin Hand Distractor is designed to be used in finger reconstruction of the thumb or the metacarpal bones I - IV after amputation or malformation.

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)

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

510(k) Number K042066