K07 2764

KLS martin L.P.

510(K) SUMMARY

DEC 20 2007

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:	21 September 2007
Device Name:	KLS Martin Xternal Fixator
Trade Name:	Xternal Fixator
Common Name:	External Fixation Device
Classification Name and Number:	External Mandibular Fixator and/or Distractor (21 CFR 872.4760)
Regulatory Class:	II
Predicate Devices:	Stryker External Fixation System (K071628) Synthes Mandible External Fixator (K050378) Bi-Phase Set, Oral, Maxillofacial Surgery (K901095)
Intended Use:	KLS Martin Xternal Fixator is intended to stabilize and provide treatment for fractures of the maxillofacial area, including severe open mandibular fractures, highly comminuted closed fractures, nonunions and delayed unions (especially associated with infection), fractures associated with infections, tumor resections, facial deformity corrections, gunshot wounds, pan facial fractures, burn maintenance, and bone grafting defects.

Device Description:

The KLS Martin Xternal Fixator consists of 3.2mm titanium pins in various lengths that are fixated to the bone. The titanium pins are held in place with titanium pin clamps and a 4mm titanium rod or can be held in place with an acrylic bar and titanium screw caps.

Technological Characteristics:

Similarities to Predicate:

The KLS Martin Xternal Fixator is very similar in fixation and providing stabilization for maxillofacial fractures as the Stryker External Fixation System (K071628) and the Synthes Mandible External Fixator (K050378)

Differences to Predicate:

The KLS Martin Xternal Fixator offers the surgeon an optional method of securing the fixation pins by utilizing an acrylic bar that is made by the surgeon.

Substantial Equivalence:

The KLS Martin Xternal Fixator is substantially equivalent in fixation and providing stabilization for maxillofacial fractures as the Stryker External Fixation System (K071628) and the Synthes Mandible External Fixator (K050378)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

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

Re: K072764
Trade/Device Name: KLS Martin Xternal Fixator
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: MQN
Dated: November 26, 2007
Received: December 3, 2007

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.

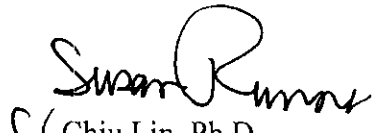
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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/industry/support/index.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): K072764

Device Name: KLS Martin Xternal Fixator

Indications For Use: KLS Martin Xternal Fixator is intended to stabilize and provide treatment for fractures of the maxillofacial area, including severe open mandibular fractures, highly comminuted closed fractures, nonunions and delayed unions (especially associated with infection), fractures associated with infections, tumor resections, facial deformity corrections, gunshot wounds, pan facialfractures, burn maintenance, and bone grafting defects.

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)

Susan Runner

K072764