K032413

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:	20 June, 2003
Device Name:	KLS-Martin Sternal Plating System
Trade Name:	Sternal Plating System
Common Name:	Plate, Fixation, Bone
Classification Name and Number:	Plate, Fixation, Bone (CFR 888.3030)
Regulatory Class:	Class II
Predicate Devices:	Lorenz Sternal Closure System (K011079) and ETHICON Surgical Stainless Steel Suture U.S.P. sizes 5 - 7
Device Description:	KLS - Martin Sternal Plating System consists of plates having a thickness of 1.0mm to 3.0mm and screws having a diameter of 2.3mm to 3.2mm.
Intended Use:	Intended use for the KLS-Martin Sternal Plating System is in stabilization and fixation of anterior chest wall fractures, including Sternal Fixation subsequent to Sternotomy and Sternal reconstructive procedures.

Technological Characteristics:

Similarities to Predicate

Intended Use for the KLS-Martin Sternal Plating System is the same as the Lorenz Sternal Closure System with Modular Screws (K011079) and the Ethicon Surgical Stainless Steel Suture. The function of these systems is to affix bony sternum fragments.

The KLS-Martin Sternal Plating System uses previously cleared Titanium Alloy (Ti-6 Al-4V) screws to affix the plates to the sternum. The plate design includes an elongated midsection to facilitate quick re-entry in subsequent thoracic procedures. The plates and screws are substantially equivalent in strength to the Lorenz Sternal Closure System with Modular Screws (K011079).

Differences to Predicate

The KLS-Martin Sternal Plating System is the same as the Lorenz Sternal Closure System with Modular Screws (K011079) with the exception that the screw is a standard bone screw and not a modular screw.

Substantial Equivalence:

The KLS-Martin Sternal System is substantially equivalent in application and function to the Lorenz Sternal Closure System with Modular Screw and Ethicon Surgical Stainless Steel Suture, U.S.P. sizes 5 to 7.

Substantial equivalence is based on comparison of performance, method of rigid bone fixation and clinical literature assessment.

Intended use of the KLS-Martin Sternal System is the same as the Lorenz Sternal Closure System with Modular Screw; the function of this system being to affix Sternal bony fragments.

Superiority of Sternal Plating to sternum wiring has been demonstrated in clinical studies. Support of this statement includes studies by Sargent *et al.*, Cheng *et al.*, Buchman *et al.*, and Ozaki *et al.*

Clinical/Non-clinical Tests:

The three clinical studies used to support the Statement of Superiority of Plating Systems are by Sargent *et al.*, Cheng *et al.* and Buchman *et al.* These studies are included in the Annex.

A fourth study "Biomechanical Study of Sternal Closure Using Rigid Fixation Techniques in Human Cadavers, Ozaki *et al.*", directly compared the KLS-Martin Sternal Plating System prototype to cerclage wire and titanium straight plates:

> Phase I - biomechanically the fixation strength of No. 5 stainless steel cerclage wires (Ethicon, Inc., Somerville, NJ) to four-hole, titanium straight plates.
>
> Phase II - biomechanically the fixation strength of No. 5 stainless steel cerclage wires to customized four-hole titanium "H" plates manufactured by KLS-Martin, as per design of Dr. Buchman.

This study is included in the Annex.

Test Conclusions:

Specifically against "Biomechanical Study of Sternal Closure Using Rigid Fixation Techniques in Human Cadavers, Ozaki *et al.*", Phase II - biomechanically the fixation strength of No. 5 stainless steel cerclage wires to customized four-hole titanium "H" plates manufactured by KLS-Martin, as per design of Dr. Buchman.

> "In our study we found a greater stiffness and a lower lateral displacement in sterna fixed with rigid custom titanium "H" plates when compared with sterna fixed with stainless steel cerclage wires."
>
> "...this study has led to the development of a rigid Sternal Plating System that is biomechanically superior to wire fixation."

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 0 2003

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

Re: K032413
Trade/Device Name: KLS-Martin Sternal 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: August 1, 2003
Received: August 5, 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) 594-4659. 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,

for Mark N Melkerson

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

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

Indications for Use

510(k) Number (if known): K032413

Device Name: KLS-Martin Sternal Plating System

Indications For Use:

KLS-Martin Sternal Plating System is intended for use in stabilization and fixation of anterior chest wall fractures including Sternal Fixation subsequent to Sternotomy and Sternal reconstructive procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhorn

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

510(k) Number K032413

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

(Optional Format 1-2-96)