KLS martin L.P. K070169

510(K) SUMMARY

MAR 26 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:	5 March 2007
Device Name:	KLS Martin Quick Disc, Sternal Talon and Sternal Plating - Sterile
Trade Name:	KLS Martin Quick Disc, KLS Martin Sternal Talon and KLS Martin Sternal Plating
Common Name:	KLS Martin Quick Disc - Plate, cranioplasty, preformed, non-alterable KLS Martin Sternal Talon - Single/multiple component metallic bone fixation appliances and accessories KLS Martin Sternal Plating System - Single/multiple component metallic bone fixation appliances and accessories
Classification Name and Number:	KLS Martin Quick Disc - 882.5330 Preformed nonalterable cranioplasty plate (CFR 882.5330) KLS Martin Sternal Talon - Single/multiple component metallic bone fixation appliances and accessories (CFR 888.3030) KLS Martin Sternal Plating System - Single/multiple component metallic bone fixation appliances and accessories (CFR 888.3030

Regulatory Class: II

Predicate Devices: KLS Martin Quick Disc (K062857)

KLS Martin Sternal Talon (K051165)

KLS Martin Sternal Plating System (K032413)

KLS Martin Rigid Fixation – Sterile (K060177)

Intended Use: To offer KLS Martin Quick Disc, KLS Martin Sternal Talon and KLS Martin Sternal Plating System in sterile packaging with the following indications for use:

K062857 KLS Martin Quick Disc is intended for reattachment of cranial bone flaps after a craniotomy, covering burr holes, and fixation of cranial fractures.

K051165 KLS Martin Sternal Talon and K032413 KLS Martin Sternal Plating System are intended for stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

Device Description:

The KLS Martin Quick Disc is a two-sided cranial closure device. The lower disc is attached to a threaded post. The upper disc is threaded down and locked on the post securely holding the bone flap in place. The KLS Martin Quick Disc diameters range from 12mm to 22mm in size

The KLS-Martin Sternal Talon is a two-piece clamping device with various foot depths and lengths that utilizes a ratcheted locking system. Each piece of the device is placed on opposing sides of the sternum and is designed to interlock providing a stabilized fixation thus allowing for various sternal widths. The device has a three position screw which allows the ratchet to open, close and lock. In an emergency situation, the device can be reopened by turning the screw to the open

position. A second emergency re-entry is provided by cut points adjacent to the screw.

KLS - Martin Sternal Plating System consists of plates having a thickness from 1.0mm to 3.0mm and screws having a diameter of 2.3mm to 3.2mm.

Technological Characteristics:

Similarities to Predicate

The KLS Martin Quick Disc, Sternal Talon and Sternal Plating System - Sterile are identical in manufacturing and materials as the KLS Martin Quick Disc (K062857), KLS Martin Sternal Talon (K051165) and KLS Martin Sternal Plating System (K032413).

The KLS Martin Quick Disc, Sternal Talon and Sternal Plating System – Sterile will be sterilized by gamma radiation and packaged in exactly the same manner as the KLS Martin Rigid Fixation – Sterile (K060177)

Difference to Predicate

The KLS Martin Quick Disc, Sternal Talon and Sternal Plating System – Sterile will be packaged sterile and will have different stock numbers from originally cleared stock numbers to identify the product as sterile.

Substantial Equivalence:

The KLS Martin Quick Disc, Sternal Talon and Sternal Plating System are substantially equivalent in manufacturing and materials to the KLS Martin Quick Disc (K062857), KLS Martin Sternal Talon (K051165), and KLS Martin Sternal Plating System (K032413) and in sterilization and packaging to the KLS Martin Rigid Fixation – Sterile (K060177)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAR 26 2007

Re: K070169
Trade/Device Name: KLS Martin Sternal Talon and KLS Martin Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS

Trade/Device Name: KLS Martin Quick Disc
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed nonalterable cranioplasty plate
Regulatory Class: Class II
Product Code: GXN
Dated: March 5, 2007
Received: March 7, 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.

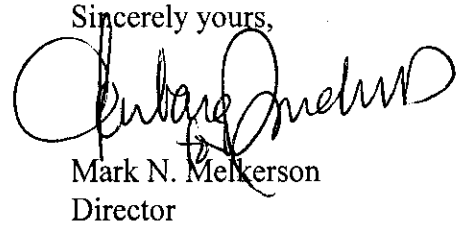
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
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): K070169

Device Name: KLS Martin Quick Disc, Sternal Talon and Sternal Plating - Sterile

Indications For Use: To offer KLS Martin Quick Disc, KLS Martin Sternal Talon and KLS Martin Sternal Plating in sterile packaging with the following indications for use:

K062857 KLS Martin Quick Disc is intended for use in the reattachment of cranial bone flaps after a craniotomy, covering burr holes, and fixation of cranial fractures.

K051165 KLS Martin Sternal Talon and K032413 KLS Martin Sternal Plating System are intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

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 K070169