



Food and Drug Administration  
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KLS Martin L.P.  
Mr. Gary Moore  
Quality Management and Regulatory Affairs Manager  
11201 Saint Johns Industrial Parkway South  
Jacksonville, Florida 32246

April 6, 2016

Re: K151983  
Trade/Device Name: KLS Martin LSS Plating System  
Regulation Number: 21 CFR 888.3010  
Regulation Name: Bone fixation cerclage  
Regulatory Class: Class II  
Product Code: JDQ, HRS  
Dated: March 4, 2016  
Received: March 8, 2016

Dear Mr. Moore:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Mark N. Melkerson -S**

Mark N. Melkerson  
Director  
Division of Orthopedic Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151983

Device Name

KLS Martin LSS Plating System

Indications for Use (Describe)

The KLS Martin LSS Plating System is to be used in conjunction with sternal closure wire for use in primary or secondary closure/repair of the sternum following sternotomy and is intended to reinforce the sternal halves and distribute wire tension.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**Section 5**  
**510(k) Summary**  
21 CFR 807.92

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**Contact Person:** Jennifer Damato  
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**Date Prepared:** April 5, 2016

**Trade Name:** KLS Martin LSS Plating System

**Common Name:** Bone fixation cerclage

**Classification:** Class II; Panel Code: 87  
21 CFR 888.3010 – Cerclage, Fixation (JDQ)  
21 CFR 888.3030 – Plate, Fixation, Bone (HRS)

**Predicate Devices:** Synthes Sternal ZipFix™ System (**K110789**)  
Ethicon Surgical Stainless Steel Suture (**K931271**)  
KLS Martin Sternal Plating System (**K032413, K070169**)

**Reference Devices:** Patient Contoured Implant – PEEK (**K072707, K151382**)  
Recon Talon (**K122860**)

**Device Description:** The KLS Martin LSS Plating System includes plates and screws that are intended to be used in conjunction with stainless steel suture wire for midline sternal closure. The LSS plates, when applied, are used to reinforce the sternal halves and mitigate the chance of sternal wire pulling through bone. The plates are manufactured from PEEK and offered in one size. The thickness of each plate ranges from 2.1 mm – 2.5 mm (minimum – maximum dimensions) and are fixated using 2.3mm titanium screws. Once the sternum is reapproximated, the midline is closed using circumferentially wrapped stainless steel suture wires. Emergent re-entry is accomplished by cutting the stainless steel suture wire.

**Indications for Use:** The KLS Martin LSS Plating System is to be used in conjunction with sternal closure wire for use in primary or secondary closure/repair of the sternum following sternotomy and is intended to reinforce the sternal halves and distribute wire tension.

**Non-Clinical Testing:** Mechanical testing was performed on the KLS Martin LSS Plating System. Simulated-use testing was conducted in various apparatus set-ups based on worst-case constructs. Three-point bending testing was performed on the LSS plate to determine both the maximum force and the path to reach the maximum force. Tensile testing was performed on the system to simulate behavior under lateral, longitudinal, and transverse shear using a PUR foam sternum model as well as metal sternum model. An additional series of tensile tests were performed on the stainless steel wire alone for comparison against the LSS plate. Torsion testing was performed to compare the locking mechanism of the LSS plate versus a titanium plate. Pressure testing was performed to test the behavior of the screw under load in the LSS plate versus a titanium plate. To simulate the loads applied to the implant during various modes of respiration, continuous oscillation testing was performed using parameters from cited literature. The mechanical testing demonstrated that the subject device construct had equivalent or better performance compared to the predicate devices.

**Clinical Testing:** Clinical testing was not necessary to support substantial equivalence.

### **Substantial Equivalence Discussion**

**Similarities to Predicates:** The KLS Martin LSS Plating System is similar to the predicate devices with respect to intended use, materials, principles of operation, and mechanical performance. The KLS Martin LSS Plating System has the same intended use for sternal closure as the predicate devices. The KLS Martin LSS Plating System has the same principles of operation as K110789 – Synthes Sternal ZipFix™ System and K931271 – Ethicon, Inc. Ethi-Pack Surgical Stainless Steel Suture for cerclage closure of the sternum. The KLS Martin LSS Plating System demonstrated equivalent performance characteristics compared to K032413, K070169 – KLS Martin Sternal Plating System and K931271 – Ethicon, Inc. Ethi-Pack Surgical Stainless Steel Suture.

**Differences to Predicates:** The KLS Martin LSS Plating System differs from K032413, K070169 – KLS Martin Sternal Plating System in that the subject device is not intended for stabilization and fixation of fractures and utilizes cerclage fixation to achieve sternal closure. The KLS Martin LSS Plating System differs from K110789 – Synthes Sternal ZipFix™ in that the subject device does not require a tensioning instrument to secure the implants. Unlike the subject device, K110789 – Synthes Sternal ZipFix™ and K931271 – Ethicon, Inc. Ethi-Pack Surgical Stainless Steel Suture do not require plates to re-distribute wire tension.

**Reference Devices:** The KLS Martin LSS Plating System includes implants manufactured from the same materials as the reference devices. The PEEK plates and titanium screws are identical in chemical composition, undergo identical manufacturing processes, and have the same permanent body contact duration as those cleared in K151382 – Patient Contoured Implant – PEEK and K122860 – Recon Talon, respectively. The screws used to fixate the PEEK plates are identical to those cleared in K122860.

**Conclusion:** The KLS Martin LSS Plating System has the same intended use and shares similar technological characteristics to the predicate devices. Non-clinical testing data demonstrates that any differences in technological characteristics do not raise new issues of safety or effectiveness. The information presented supports substantial equivalence of the KLS Martin LSS Plating System to the predicate devices.