



Food and Drug Administration
10903 New Hampshire Avenue
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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: K153482
Trade/Device Name: KLS Martin Thoracic 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
Dated: March 3, 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)

K153482

Device Name

KLS Martin Thoracic Plating System

Indications for Use (Describe)

The KLS Martin Thoracic Plating System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Section 5
510(k) Summary
21 CFR 807.92

Submitter: KLS Martin LP
11201 Saint Johns Industrial Pkwy S.
Jacksonville, FL 32246

Contact Person: Jennifer Damato
Director of Quality MGT & Regulatory Affairs
Phone: 800-625-1557
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Date Prepared: April 4, 2016

Trade Name: KLS Martin Thoracic Plating System

Common Name: Plate, Fixation, Bone

Classification: Single/multiple component metallic bone fixation appliances and accessories
Class II, 21 CFR 888.3030, Product Code HRS

Predicates: Biomet Microfixation Thoracic Fixation System (**K142823**)
KLS-Martin Sternal Plating System (**K032413 / K070169**)
KLS Martin Recon Talon (**K122860**)

Device Description:

The KLS Martin Thoracic Plating System includes metallic plates and screws that provide rigid fixation to fractures, planned osteotomies, and can be used for reconstructive procedures in the thoracic anatomy. The implants are available non-sterile or sterile in multiple shapes and sizes. Plates are manufactured from CP Titanium (ASTM F67:2013) and range in thickness from 1.0 – 3.0mm. Screws are manufactured from Ti-6Al-4V (ASTM F136:2013) and range in diameter from 2.3 – 3.2mm with lengths from 7 – 17mm. The system also includes the necessary instruments to facilitate placement of the implants.

Indications for Use:

The KLS Martin Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies.

Contraindications: 1. Active Infection. 2. Not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical or lumbar spine. 3. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone or latent infections. 4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions. 5. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.

Substantial Equivalence Discussion:**Similarities to Predicate Devices**

The subject and predicate devices include metallic plates and screws intended to provide rigid fixation of bone in the thoracic anatomy. All implant systems are manufactured from CP Titanium and Ti-6Al-4V and are implanted using the same method of fixation. The subject device incorporates locking plate and screw characteristics similar to the KLS Martin Recon Talon – K122860, and undergoes identical manufacturing and sterilization processes as the KLS Martin Recon Talon – K122860 and the KLS-Martin Sternal Plating System – K032413 / K070169.

Differences to Predicate Devices

The subject device offers implants in sterile packaging and additional plate shapes from the primary predicate, Biomet Microfixation Thoracic Fixation System – K142823. The subject device differs from the KLS Martin Recon Talon – K122860 and KLS-Martin Sternal Plating – K032413 / K070169 with expanded indications for use in lateral and posterior chest wall fixation and includes additional plate shapes for rib fractures.

Non-Clinical Performance Data:

Static and dynamic 4-point bending tests were performed in accordance with ASTM F382. The strength properties of the subject plates were compared against the predicate plates. Results met or exceeded the defined test conditions and demonstrate that the performance of the subject plates is substantially equivalent to the predicate devices.

Clinical Performance Data:

Clinical testing was not necessary for the determination of substantial equivalence.

Conclusion:

The KLS Martin Thoracic Plating System has the same intended use, same principles of operation, and similar technological features compared to the predicate devices. Any differences in technological features between the subject and predicate devices do not raise different questions of safety and effectiveness. The non-clinical performance data presented supports substantial equivalence of the KLS Martin Thoracic Plating System to the predicate devices.