March 29, 2023

KLS-Martin L.P.
Pam Martin
Regulatory Affairs Project Manager
11201 Saint Johns Industrial Pkwy S
Jacksonville, Florida 32246

Re: K222397
Trade/Device Name: KLS Martin Level One Rib Fixation 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: February 24, 2023
Received: March 1, 2023

Dear Pam Martin:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jesse Muir -S

For: Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K222397

Device Name

KLS Martin Level One Rib Fixation System

Indications for Use *(Describe)*

The KLS Martin Level One Rib Fixation System is indicated for use in the stabilization and rigid fixation of rib fractures in the chest wall including reconstructive procedures, trauma, or planned osteotomies in patients 18 years of age or older.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) #: K222397

510(k) Summary

Prepared on: 2023-03-28

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	KLS-Martin L.P.
Applicant Address	11201 Saint Johns Industrial Pkwy S Jacksonville FL 32246 United States
Applicant Contact Telephone	800-625-1557
Applicant Contact	Ms. Melissa Bachorski
Applicant Contact Email	rapm_na@klsmartin.com
Correspondent Name	KLS-Martin L.P.
Correspondent Address	11201 Saint Johns Industrial Pkwy S Jacksonville FL 32246 United States
Correspondent Contact Telephone	800-625-1557
Correspondent Contact	Ms. Pam Martin
Correspondent Contact Email	pmartin@klsmartin.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	KLS Martin Level One Rib Fixation System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code	HRS

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K153482	KLS Martin Thoracic Plating System	HRS
K151983	KLS Martin Longitudinal Sternal Stabilization (LSS) System	JDQ
K081623	Synthes MatrixRIB Fixation System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The KLS Martin Level One Rib Fixation System is comprised of PEEK plates and titanium locking screws intended to provide rigid fixation of bone in the thoracic anatomy. The PEEK plates are pre-contoured to accommodate patient anatomy and are offered in plate thicknesses of 2 mm – 3 mm. The PEEK plates are compatible with the Ti-6Al-4V (ASTM F136) 2.3 mm x 7 mm multidirectional locking screws offered in the system. The plates are manufactured from PEEK (ASTM F2026). The system includes the necessary instrumentation

to facilitate implantation.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The KLS Martin Level One Rib Fixation System is indicated for use in the stabilization and rigid fixation of rib fractures in the chest wall including reconstructive procedures, trauma, or planned osteotomies in patients 18 years of age or older.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The subject device differs from the primary predicate, KLS Martin Thoracic Plating System (K153482), in indications for use. The addition of the Transitional Adolescent B patient population to the subject device indications does not constitute a new intended use because no special considerations are being given, or required, for the Category B adolescents compared to adults. The anatomical area of use for the subject device is exclusive to the ribs, whereas the primary predicate device is cleared for the chest wall including sternum.

Technological Comparison 21 CFR 807.92(a)(6)

Similarities to Predicate:
Both the subject and primary predicate devices are intended for stabilization and rigid fixation of bone in the thoracic anatomy. The design / shape of the PEEK rib plates is similar to the rib plates evaluated in the primary predicate. Both the subject and primary predicate devices are fixated with titanium screws.

Differences from Predicate:
The subject device plates are made from PEEK whereas the primary predicate device plates are made from CP Titanium. The subject device is limited for use in the rib, whereas the primary predicate device was cleared for use in the chest wall, including sternum.

Reference Devices:
The KLS Martin LSS Plating System (K151983) has been included as a reference device to leverage biocompatibility data for the subject device. The KLS Martin Level One Rib Fixation System includes implants manufactured from the same materials as the reference device, PEEK. 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 K151983 – KLS Martin LSS Plating System.

The Synthes MatrixRIB Fixation System (K081623) has been included as a reference device to compare mechanical performance against the subject device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-Clinical Performance Data:
Comparative head-to-head bench testing was conducted to determine whether the subject device performs equivalent to or better than the primary predicate device in pull-out system testing. Static and dynamic testing was compared to the reference device, Synthes MatrixRIB Fixation System (K081623). The testing met all predetermined acceptance criteria and the results demonstrate that the subject device's performance is substantially equivalent to both the primary predicate device and the reference device. Biological safety risk assessments in compliance with ISO 10993-1 :2018 were completed on the subject devices and concluded the devices are biocompatible and appropriate for their intended use.

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

Conclusions:
The KLS Martin Level One Rib Fixation System has the same intended use and similar technological characteristics as the primary predicate device. Technological differences have been addressed through performance data from the predicate and reference devices. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence.