July 12, 2024

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

Re: K241018
Trade/Device Name: KLS Martin Orthopedic Implants - MR Conditional
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC, JDQ
Dated: April 12, 2024
Received: April 15, 2024

Dear Katie Ruthland:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Shumaya Ali -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241018

Device Name

KLS Martin Orthopedic Implants - MR Conditional;
K032413: KLS Martin Sternal Plating System;
K040598: KLS Martin Hand Plating System;
K051165: KLS Martin Sternal Talon;
K070169: KLS Martin Sternal Talon & KLS Martin Sternal Plating System - Sterile;
K122860: Recon Talon ;
K141489: LINOS MOH Hand Plating System ;
K151983: KLS Martin LSS Plating System ;
K153482: KLS Martin Thoracic Plating System ;
K161259: KLS Martin Cannulated Headless Screws;
K170124: Level One Hand Plating System ;
K221938: KLS Martin Pure Pectus System ;
K222397: KLS Martin Level One Rib Fixation System ;
K222624: KLS Martin LINOS Wrist System

Indications for Use *(Describe)*

KLS Martin Sternal Plating System (K032413):
The 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.

KLS Martin Hand Plating System (K040598):
The KLS Martin Hand Plating System is used for stabilization and fixation of fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, wrist, fingers, feet, ankles and toes.

KLS Martin Sternal Talon (K051165):
The KLS Martin Sternal Talon is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

KLS Martin Sternal Talon & KLS Martin Sternal Plating System - Sterile (K070169):
To offer KLS Martin Sternal Talon and KLS Martin Sternal Plating in sterile packaging with the following indications for use: 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.

Recon Talon (K122860):
The KLS Martin Recon Talon is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

LINOS MOH Hand Plating System (K141489):
The LINOS MOH Hand Plating System is used for stabilization and fixation of fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, wrist, fingers, feet, ankles and toes.

KLS Martin LSS Plating System (K151983):
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.

KLS Martin Thoracic Plating System (K153482):
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.

KLS Martin Cannulated Headless Screws (K161259):
KLS Martin Cannulated Headless Screws are intended for the treatment of fractures, osteotomies, arthrodeses, and nonunions of small bones in the hand, wrist, foot, and ankle.

Level One Hand Plating System (K170124):
The Level One Hand Plating System is used for stabilization and fixation of fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, wrist, fingers, feet, ankles and toes.

KLS Martin Pure Pectus System (K221938):
The KLS Martin Pure Pectus System is indicated for use in surgical procedures to repair pectus excavatum. It is indicated for use in adult and pediatric (children and adolescents) populations.

KLS Martin Level One Rib Fixation System (K222397):
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.

KLS Martin LINOS Wrist System (K222624):
The KLS Martin LINOS Wrist System is indicated for use in forearm fractures, osteotomies, and arthrodeses. It is intended for adults, and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by fixation.

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.

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510(k) #:

510(k) Summary

Prepared on: 2024-04-12

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	KLS-Martin L.P.
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Correspondent Contact	Ms. Katie Rutland
Correspondent Contact Email	katie.rutland@klsmartin.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	KLS Martin Orthopedic Implants - MR Conditional; K032413: KLS Martin Sternal Plating System; K040598: KLS Martin Hand Plating System; K051165: KLS Martin Sternal Talon; K070169: KLS Martin Sternal Talon & KLS Martin Sternal Plating System - Sterile; K122860: Recon Talon ; K141489: LINOS MOH Hand Plating System ; K151983: KLS Martin LSS Plating System ; K153482: KLS Martin Thoracic Plating System ; K161259: KLS Martin Cannulated Headless Screws; K170124: Level One Hand Plating System ; K221938: KLS Martin Pure Pectus System ; K222397: KLS Martin Level One Rib Fixation System ; K222624: KLS Martin LINOS Wrist System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	888.3030
Product Code(s)	HRS, HWC, JDQ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K032413	KLS Martin Sternal Plating System	HRS
K040598	KLS Martin Hand Plating System	HRS
K051165	KLS Martin Sternal Talon	HRS
K070169	KLS Martin Sternal Talon & KLS Martin Sternal Plating System	HRS
K122860	Recon Talon	HRS
K141489	LINOS MOH Hand Plating System	HRS
K151983	KLS Martin LSS Plating System	JDQ
K153482	KLS Martin Thoracic Plating System	HRS
K161259	KLS Martin Cannulated Headless Screws	HWC
K170124	Level One Hand Plating System	HRS
K221938	KLS Martin Pure Pectus System	HRS
K222397	KLS Martin Level One Rib Fixation System	HRS
K222624	KLS Martin LINOS Wrist System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

KLS Martin Sternal Plating System (K032413):
The KLS Martin Sternal Plating System consists of titanium plates ranging in thickness from 1.0mm – 3.0mm and screws ranging in diameter from 2.3mm – 3.2mm.

KLS Martin Hand Plating System (K040598):
The KLS Martin Hand Plating System consists of titanium plates ranging in thickness from 0.6mm – 3.0mm and screws ranging in diameter from 1.0mm – 2.7mm.

KLS Martin Sternal Talon (K051165):
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. The KLS Martin Sternal Talon is manufactured from titanium alloy (Ti-6Al-4V).

KLS Martin Sternal Talon & KLS Martin Sternal Plating System - Sterile (K070169):
The KLS Martin Sternal Talon (K051165) 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. The KLS Martin Sternal Talon is manufactured from titanium alloy (TI-6Al-4V). The KLS Martin Sternal Plating System (K032413) consists of titanium plates ranging in thickness from 1.0mm – 3.0mm and screws ranging in diameter from 2.3mm – 3.2mm. The screws are used to affix the plates to the sternum. Plate design features include an elongated midsection to facilitate quick re-entry in subsequent thoracic procedures.

Recon Talon (K122860):
The KLS Martin Recon Talon is a two-piece clamping device, which has on either end an attached plate. Plate thickness ranges from

1.0mm to 3.0mm and screw diameter ranges from 2.3mm to 3.2mm. The two-piece clamping device utilizes a ratcheted locking system. Each piece of the device is affixed to opposing sides of the sternum and interlocks to provide stabilized fixation. The device has a three-position screw, allowing the ratchet to open, close, and lock. In an emergency situation the device can be reopened by turning the screw to the open position. Secondary emergency re-entry is provided by cut points adjacent to the screw.

LINOS MOH Hand Plating System (K141489):
The LINOS MOH Hand Plating System consists of titanium plates ranging in thickness from 0.6mm – 3.0mm and screws ranging in diameter from 1.0mm – 2.7mm. Plate features include a low profile with angulated-locking threaded screw holes. Screws are either locking or non-locking.

KLS Martin LSS Plating System (K151983):
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.

KLS Martin Thoracic Plating System (K153482):
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.

KLS Martin Cannulated Headless Screws (K161259):
The KLS Martin Cannulated Headless Screws (CHS) system is comprised of headless cannulated screws intended for bone fixation in the treatment of fractures, non-unions, osteotomies, or to aid in small joint fusions of the hand, wrist, foot, and ankle. Bone fixation is achieved by proximal and distal threads designed with different pitches that, when inserted into the bone, cause compression of the bone fragments for bone reduction, stability, and healing. Cannulation of the screws is designed to allow the user to insert the screw over the guide wire for proper placement prior to compression. The CHS system offers screws in various diameters, overall lengths, and thread lengths to accommodate different sizes and types of bone reduction, such as scaphoid fractures and non-unions. The screws are self drilling and self-tapping to eliminate the need for drilling a pilot hole prior to implantation. All screws are manufactured from Ti-6Al-4V (ASTM F136:2013).

Level One Hand Plating System (K170124):
The Level One (L1) Hand Plating System includes metallic plates, washers, and screws intended for small bone fixation. Plates are pre-contoured to accommodate patient anatomy, available in various shapes and range in thickness from 0.6mm - 3.0mm and are compatible with the standard and multidirectional locking screws offered in the system. Screws are self tapping, available in a standard or multidirectional locking configuration and range in diameter from 1.0mm - 2.7mm with lengths from 2mm - 32mm. Standard screws may be used alone or in conjunction with the washers or plates for small fragment osteosynthesis. Implants are manufactured from CP Titanium (ASTM F67) or Ti-6Al-4V (ASTM F136).

KLS Martin Pure Pectus System (K221938):
The KLS Martin LP Pure Pectus system consists of metallic implants comprised of straight and angled pectus bars and connector bars that provide support to the thoracic cavity undergoing repair for pectus excavatum. The implants are provided non-sterile in multiple sizes and are manufactured using traditional manufacturing methods. Pectus bars are manufactured from CP Titanium. Connector bars are manufactured from Ti-6Al-4V. The system also includes the necessary instruments to facilitate placement of the implants.

KLS Martin Level One Rib Fixation System (K222397):
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 Fl 36) 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.

KLS Martin LINOS Wrist System (K222624):
The KLS Martin LINOS Wrist System consists of metallic plates used in conjunction with bone screws and locking pins intended for the internal fixation, alignment, stabilization, reconstruction, and/or corrective osteotomies of the distal radius and/or ulna. Plates are manufactured from Ti-6Al-4V or CP Titanium. Plates are pre-contoured to accommodate patient anatomy and are available in various shapes and dimensions. The system also includes the necessary instruments to facilitate placement of the implants.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

KLS Martin Sternal Plating System (K032413):
The 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.

KLS Martin Hand Plating System (K040598):
The KLS Martin Hand Plating System is used for stabilization and fixation of fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, wrist, fingers, feet, ankles and toes.

KLS Martin Sternal Talon (K051165):
The KLS Martin Sternal Talon is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

KLS Martin Sternal Talon & KLS Martin Sternal Plating System - Sterile (K070169):
To offer KLS Martin Sternal Talon and KLS Martin Sternal Plating in sterile packaging with the following indications for use: 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.

Recon Talon (K122860):
The KLS Martin Recon Talon is intended for use in stabilization and fixation of anterior chest wall fractures including sternal fixation subsequent to sternotomy and sternal reconstructive procedures.

LINOS MOH Hand Plating System (K141489):
The LINOS MOH Hand Plating System is used for stabilization and fixation of fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, wrist, fingers, feet, ankles and toes.

KLS Martin LSS Plating System (K151983):
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.

KLS Martin Thoracic Plating System (K153482):
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.

KLS Martin Cannulated Headless Screws (K161259):
KLS Martin Cannulated Headless Screws are intended for the treatment of fractures, osteotomies, arthrodeses, and nonunions of small bones in the hand, wrist, foot, and ankle.

Level One Hand Plating System (K170124):
The Level One Hand Plating System is used for stabilization and fixation of fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, wrist, fingers, feet, ankles and toes.

KLS Martin Pure Pectus System (K221938):
The KLS Martin Pure Pectus System is indicated for use in surgical procedures to repair pectus excavatum. It is indicated for use in adult and pediatric (children and adolescents) populations.

KLS Martin Level One Rib Fixation System (K222397):
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.

KLS Martin LINOS Wrist System (K222624):
The KLS Martin LINOS Wrist System is indicated for use in forearm fractures, osteotomies, and arthrodeses. It is intended for adults, and children (2-12 years) and adolescents (12-21 years) in which growth plates have fused or in which growth plates will not be crossed by fixation.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use for the subject and predicate devices are identical. The basis of this submission is to support the conditional safety and labeling modification of the subject device, KLS Martin Orthopedic Implants – MR Conditional, in the magnetic resonance environment.

Technological Comparison

21 CFR 807.92(a)(6)

The subject and predicate devices share identical technological characteristics which were previously evaluated in each predicate device included in this bundled submission. There have been no significant changes to the previously cleared devices that would impact safety and effectiveness with regard to design, mechanical and engineering performance, manufacturing processes, materials, sterility, packaging and shelf life, and biocompatibility.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical testing has been provided to support the conditional safety of the subject devices in the MR environment. Hazards addressed include magnetically induced displacement force (ASTM F2052-21) and torque (ASTM F2213-17), image artifacts (ASTM F2119-07, R2013), and RF-induced heating (ASTM F2182-19e2).

Not Applicable

Computational modeling and simulation (CM&S) was used to estimate ex-vivo and in-vivo temperature rise due to RF-induced heating for the entire portfolio of KLS Martin thoracic and hand osteosynthesis implants, which is the focus of this pre-submission. Simulations of RF-induced heating at 1.5 T/64 MHz and 3 T/128 MHz were conducted in lieu of physical testing according to ASTM F2182-19e2 using MED Institute's FDA-qualified Medical Device Development Tool (MDDT) and in a clinically relevant position within the Duke virtual human anatomy. Various in-vivo device positions and landmarks of the Duke virtual human anatomy with the worst-case single and multiple devices were then simulated in 10 cm increments in each MRI system to determine the worst-case scenario for in-vivo RF-induced heating. The worst-case device, in-vivo position and landmark location for each MRI system for in-vivo RF-induced heating at a whole-body averaged specific absorption rate (wbSAR) of 2 W/kg or head SAR of 3.2 W/kg are determined. Fractional wbSAR or head SAR for an hour-long scanning session while maintaining a temperature rise of below 6 °C were determined for the worst-case devices within the Duke (Tables 3 to 12 in the test report) to align with the most recent FDA guidance document for testing and labeling of medical devices for safety in the magnetic resonance environment. Scanning conditions and guidelines for anatomical regions that can be safely scanned for an hour of continuous RF at wbSAR of 2 W/kg or head SAR of 3.2 W/kg were also determined. Therefore, the devices listed in the KLS Martin Orthopedic portfolio can be safely scanned under the conditions presented in the labeling.