December 11, 2025

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

Re: K250988
Trade/Device Name: KLS Martin Pure Pectus 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: December 4, 2025
Received: December 4, 2025

Dear Meraj Akhtar:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Thomas Mcnamara -S

For: Christopher Ferreira, M.S.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250988

Please provide the device trade name(s).

KLS Martin Pure Pectus System

Please provide your Indications for Use below.

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.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K250988

510(k) Summary

Prepared on: 2025-12-03

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. Meraj Akhtar
Correspondent Contact Email	rapm_na@klsmartin.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	KLS Martin Pure Pectus 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

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221938	KLS Martin Pure Pectus System	HRS
K241018	KLS Martin Orthopedic Implants – MR Conditional	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The KLS Martin 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.

The purpose of this submission is as follows:

1. Line extension to include longer pectus bar sizes for both angled and straight pectus bars ranging greater than 380 mm and less than/equal to 500 mm

2. Add "MR Conditional" to the device labeling for the angled and straight pectus bars ranging greater than 380 mm and less than/equal to 500 mm used in conjunction with connector bars

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

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.

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

The indications for use for the subject and primary device are identical in that they include metallic implants intended to support the thoracic anatomy. They are both intended for use in adult and pediatric (children and adolescents) populations.

Technological Comparison 21 CFR 807.92(a)(6)

Similarities to Predicate Device:
The subject and predicate devices have the same fundamental technologies in that they are both metallic implants for use in surgical procedures of the thoracic and sternal region to repair pectus excavatum . Both devices are manufactured in a variety of lengths and configurations to provide the physician with different sizing options. Both devices are off-the-shelf products provided non-sterile and require the end-user to process the implants using validated cleaning and sterilization methods prior to use. The sterilization methods, packaging, and shelf-life information remains unchanged from the predicate. Both devices are manufactured from titanium, a well-known biocompatible material.

Target Population:
The subject device, as well as the primary predicate device, K221938, were cleared for use in the adult and pediatric populations, specifically in the following pediatric subpopulations:

· Children (2 years of age to < 12 years of age)
· Adolescents (12 years of age – 21 years of age)

Differences from Predicate Device:
Specifications
The predicate device, KLS Martin Pure Pectus system includes the pectus bars ranging from 200 mm to 380 mm in length. The subject device will be a modification to the pectus bars to include additional sizing options ranging in greater than 380 mm and less than/equal to 500 mm. The cross-sections of the subject and predicate pectus bars are identical to each other, only the extended lengths are different. The modified pectus bars described do not alter the safety and efficacy of the intended use for the KLS Martin Pure Pectus system. The device usage is identical; there are no changes in formulation, processing, or sterilization. The manufacturing process used in the subject device is similar to the final finished form of the pectus bars cleared in K221938. We determined that extending the pectus bar length ranging in greater than 380 mm and less than/equal to 500 mm, will not alter the safety and effectiveness of the device. There have been no changes to the sterility procedures of the device.

MR Environment Safety Information:
Non-clinical testing has been performed to support the conditional safety of the subject device 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).

The longer pectus bars (subject device) have met all acceptance criteria to substantiate the labeling claim of "MR Conditional" in the magnetic resonance environment. Therefore, the devices listed in the KLS Martin Pure Pectus portfolio can be safely scanned under the conditions presented in the labeling.

Conclusion:
Based on the questions above as well as conformance to FDA-recognized standards, safety and effectiveness has been demonstrated. The additional length sizes for the pectus bars will be included in the cleared KLS Martin Pure Pectus system (K221938). The subject device and predicate device have the same intended use, same principles of operation, and technological characteristics. No new or different questions of safety or effectiveness were identified, which supports the conclusion that the subject device is substantially equivalent to the predicate device.

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

Non-Clinical Performance Data:
In accordance with ASTM F382-24, static and dynamic four-point bending tests were conducted to compare the mechanical properties of the longer pectus bars (subject device) to the predicate device, KLS Martin Pure Pectus system (K221938). The testing met all acceptance criteria, and the results demonstrate that the longer pectus bar performance is substantially equivalent to the cleared pectus bars in K221938.

Biocompatibility:
With the exception of an alternative manufacturing processing aide, the manufacturing process steps, raw materials, and cleaning methods for the longer pectus bars are identical to the cleared predicate device KLS Martin Pure Pectus system (K221938). Additional ISO 10993-23 Irritation testing (intracutaneous reactivity test) was performed to address the new manufacturing processing aide. Refer to attachments Biocompatibility Summary and Biocompatibility Justification Pectus Longer Bars in the "Biocompatibility" section of the eSTAR.

MR Environment Safety Information:
Non-clinical testing has been performed to support the conditional safety of the subject device 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).

The longer pectus bars (subject device) have met all acceptance criteria to substantiate the labeling claim of "MR Conditional" in the magnetic resonance environment. Therefore, the devices listed in the KLS Martin Pure Pectus portfolio can be safely scanned under the conditions presented in the labeling.

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

Conclusions:
Based on the evaluation, conformance to FDA-recognized standards, and the performance testing provided in this submission, device safety and effectiveness have been demonstrated. KLS Martin Pure Pectus System has the same intended use, same principles of operation, and similar technological features compared to the predicate device. Any differences in technological features between the subject and predicate device do not raise different questions of safety and effectiveness. The non-clinical performance data presented supports substantial equivalence of KLS Martin Pure Pectus System to the predicate device.