February 20, 2026

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

Re: K253660
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: November 20, 2025
Received: November 20, 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

CHRISTOPHER FERREIRA -S

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.	K253660

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 and other anterior chest wall deformities. 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 (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K253660

510(k) Summary

Prepared on: 2026-02-17

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 #	Trade Name (Primary Predicate listed first, then Reference Devices)	Product Code
K073556	MedXpert P.E.S. (Pectus Excavatum System), MedXpert STRATOS	HRS
K221938	KLS Martin Pure Pectus System	HRS
K250620	KLS Martin Ixos System	HRS
K222624	KLS Martin LINOS Wrist System	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 and other anterior chest wall deformities. 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 the Pectus Stabilizer

2. Add "MR Conditional" to the device labeling for the Pectus Stabilizer used in conjunction with pectus bar.

3. Expand the Indications for Use to include other anterior chest wall deformities such as Pectus Carinatum and Pectus Arcuatum

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 and other anterior chest wall deformities. 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 are similar to the predicate device with the exception that the subject device is indicated for child and adolescent pediatric subpopulations. The predicate device's indications for use does not include any information describing the intended patient population. Though the predicate device does not specify age, these systems are commonly used across similar populations. This does not change the fundamental surgical purpose.

Technological Comparison

21 CFR 807.92(a)(6)

Similarities to Predicate Device:
The subject and predicate device share the same fundamental technologies in that they are both metallic implants for use in surgical procedures of the thoracic and sternal region to repair sternal deformities.
The subject and predicate devices to improve rotational stability of a single pectus bar. They are all permanent implants with a contact duration of >30 days and are manufactured from materials with a history of clinical use and demonstrated biocompatibility. 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.

Differences from Predicate Device:
Specifications
The subject device is manufactured from Ti-6Al-4V (ASTM F136) whereas the predicate device is manufactured from 316L Stainless Steel. Performance testing provided in the Performance Testing - Bench section demonstrated that the differences in material does not affect the safety and effectiveness of the subject devices and can be determined substantially equivalent.

Comparison to Reference Device:
The subject device is a line extension of K221938 to include stabilizer bars. The manufacturing process used for the subject device is similar to the connector bars cleared in reference device, K221938. The surface finishing step Type II/III anodization is identical to the validated anodization processes cleared for the reference devices, K250620 and K222624.
The subject device, as well as the reference device, K221938, are 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)

MR Environment Safety Information:
Non-clinical testing has been performed on the pectus bar used in conjunction with the pectus stabilizer 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 subject device has met all acceptance criteria to substantiate the labeling claim of "MR Conditional" in the magnetic resonance environment. Therefore, the KLS Martin Pure Pectus System 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, along with the performance data compared with the predicate, K073556, safety and effectiveness has been demonstrated. The subject device has the same intended use, same principles of operation, and similar technological characteristics as the predicate device. Technological differences have been addressed through performance data between the subject and predicate device. The non clinical performance data presented supports substantial equivalence of the subject device to the predicate device. 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 subject device to the predicate device, MedXpert P.E.S. (Pectus Excavatum System) MedXpert STRATOS (K073556). The testing met all acceptance criteria, and the results demonstrate that the subject device performance is substantially equivalent to the predicate device.

Biocompatibility:
The subject device is manufactured from titanium alloy (Ti-6Al-4V), the same composition specifications as the cleared connector bars within the KLS Martin Pectus System, K221938. In accordance with ISO 10993-1:2018 and the FDA Guidance on Biological Evaluation of Medical Devices, the biological risk associated with the anodized stabilizer is negligible, and no additional biocompatibility testing is warranted. Therefore, the anodized stabilizer is considered biocompatible for its intended use and contact duration and is not expected to elicit any adverse biological response.

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 subject device has 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 System 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. The subject device has the same intended use, same principles of operation, and similar technological characteristics as the predicate device. Technological differences have been addressed through performance data between the subject and predicate device. The non-clinical performance data presented supports substantial equivalence of the subject device to the predicate device. No new or different questions of safety or effectiveness were identified, which supports the conclusion that the subject device system is substantially equivalent to the predicate device.