February 20, 2026

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

Re: K254162
Trade/Device Name: KLS Martin Ixos 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, HWC
Dated: December 22, 2025
Received: December 22, 2025

Dear Liza Gordillo:

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.	K254162

Please provide the device trade name(s).

KLS Martin Ixos System

Please provide your Indications for Use below.

The KLS Martin Ixos system is indicated for use in forearm fractures, osteotomies, and arthrodeses. This system is intended for adults, as well as adolescents (12-21 years) and children (2-12 years) in which growth plates have fused or in which growth plates will not be crossed by fixation.

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) #:

510(k) Summary

Prepared on: 2025-12-22

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. Liza Gordillo
Correspondent Contact Email	rapm_na@klsmartin.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	KLS Martin Ixos System
Common Name	Single/multiple component metallic bone fixation appliances and accessories
Classification Name	Plate, Fixation, Bone
Regulation Number	21 CFR 888.3030 - Single/multiple component metallic bone fixation applia
Product Code(s)	HRS (Class 2) - Plate, Fixation, Bone; HWC (CLASS 2) - SCREW, FIXATI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222624	KLS Martin LINOS Wrist System	HRS
K143749	Arthrex Distal Radius System	HRS
K092247	Synthes Locking Hand Plates	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The KLS Martin Ixos System consists of metallic plates used in conjunction with bone screws and locking pins intended for the internal fixation, alignment, stabilization, and reconstruction of the radius and/or ulna. Plates are manufactured from Ti-6Al-4V and are available in various shapes and dimensions. The system also includes the necessary instruments to facilitate placement of the implants. The manufacturing process, sterilization methods, materials and packaging are identical to those of the cleared predicate device, KLS Martin LINOS Wrist System (K222624).

The purpose of this premarket notification is to expand the Ixos system to include anatomically pre-contoured plates designed to conform to the dorsal aspect of the radius, the distal ulna, and the shaft portions of both the radius and ulna. These plates will be available in both left and right configurations. In addition, new sizers will be introduced to the current Ixos system to assist with intraoperative selection and placement.

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

The KLS Martin Ixos system is indicated for use in forearm fractures, osteotomies, and arthrodeses. This system is intended for adults, as well as adolescents (12-21 years) and children (2-12 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 of the subject and primary predicate device are identical.

Technological Comparison 21 CFR 807.92(a)(6)

SIMILARITIES TO PRIMARY PREDICATE
The subject and predicate devices have the same fundamental technologies in that they are all designed for the internal fixation, alignment, stabilization, and reconstruction of the radius and/or ulna. They are manufactured from the same materials using the same manufacturing methods. All plates are pre-contoured to accommodate patient anatomy.

The device has the same technological characteristics (i.e., design, material, chemical composition, principle of operation, energy source, etc.) as the primary predicate device, K222624 LINOS Wrist System.

DIFFERENCES FROM PRIMARY PREDICATE
The only difference between the subject and predicate devices are the implant shapes. The subject devices are anatomically pre-contoured plates designed to conform to the dorsal aspect of the radius, the distal ulna, and the shaft portions of both the radius and ulna. The predicate devices have a variety of designs, including palmar radius plates, ulnar plates, dorsal and dorsolateral plates.

CONCLUSIONS
The KLS Martin Ixos system has the same intended use and the same technological characteristics as the primary predicate device, the KLS Martin LINOS Wrist System. Non-clinical testing demonstrates that the subject device is as safe, as effective, and performs as well as or better than the primary and secondary predicates.

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

NON-CLINICAL PERFORMANCE DATA
Comparative static and dynamic mechanical performance testing of the subject device and the reference devices were completed in accordance with ASTM F382 Standard Specifications and Test Methods for Metallic Bone Plates.

MR Environment Safety Information
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).

CLINICAL PERFORMANCE DATA
Not Applicable

CONCLUSIONS
The results of comparative static and dynamic performance testing demonstrate that the subject devices performed as well as the reference devices and are therefore substantially equivalent.