November 14, 2025

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

Re: K250865
Trade/Device Name: KLS Martin IPS Forearm 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, PBF, HWC
Dated: March 21, 2025
Received: March 21, 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 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,

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.	K250865

Please provide the device trade name(s).

KLS Martin IPS Forearm System

Please provide your Indications for Use below.

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

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) #: K250865

510(k) Summary

Prepared on: 2025-10-15

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 IPS Forearm System
Common Name	Single/multiple component metallic bone fixation appliances and accessories Smooth or threaded metallic bone fixation fastener
Classification Name	Plate, Fixation, Bone (primary); Orthopaedic Surgical Planning and Instrument Guides; Screw, Fixation, Bone
Regulation Number	888.3030 (primary) / 888.3040
Product Code(s)	HRS, PBF, HWC

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
K210731	KLS Martin Individual Patient Solutions	JEY
K192979	KLS Martin IPS Thoracic Planning System	PBF
K170124	KLS Martin Level One Hand Plating System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The KLS Martin Individual Patient Solutions (IPS) Forearm System is comprised of additively manufactured, patient-specific models, guides and metallic bone plates. The plates will be used in conjunction with previously cleared metallic bone screws and locking pins for internal fixation, alignment, stabilization, reconstruction, and/or corrective osteotomies of the radius and/or ulna. The devices are designed and manufactured to be patient-specific based on the electronic medical image of the patient's anatomy; with input from the physician during virtual planning, prior to finalization, and prior to production of the device. The physician provides input for model manipulation and interactive feedback by viewing digital models of planned outputs that are modified by trained KLS Martin engineers during the planning session. For each design iteration, verification is performed by virtually fitting the generated implant over a 3D model of the patient's anatomy to ensure its dimensional properties allow an appropriate fit.

Implants are provided non-sterile and are manufactured using additive methods from Ti-6Al-4V. The system also includes the necessary fixation devices and instruments to facilitate placement of the implants.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use of the subject device, KLS Martin IPS Forearm System, is identical to the primary predicate device, KLS Martin LINOS Wrist System (K222624). The potential impact on substantial equivalence of each technological difference was addressed through risk analysis and verification and validation testing.

Technological Comparison

21 CFR 807.92(a)(6)

Similarities to Primary Predicate Device
The subject and predicate devices have the same fundamental technologies in that they are both designed for use in surgical procedures of the radius and/or ulna to repair forearm fractures, osteotomies, and arthrodeses in the adult and pediatric populations.

Both implants are provided non-sterile and require the end-user to process the implants using validated cleaning and sterilization methods prior to use.

The specifications for the subject and primary predicate devices are similar with respect to plate width, length, and thickness. The subject device falls within the previously identified range in width for the plates in both the radius and the ulna.

Both the subject and primary predicate devices are manufactured from Ti-6Al-4V (ASTM F136) and are attached to the radius and ulna using metallic bone screws and locking pins.

Differences from Primary Predicate Device
The subject device dimensions differ from the predicate by offering additional device sizes. Any differences in specifications between the subject and predicate devices have been evaluated, and mechanical bench testing was performed on the worst-case plate designs to demonstrate that the design expansion does not impact the determination for substantial equivalence.

Comparison to Reference Devices
The subject device consists of a similar set of components and production processes as the reference devices, K192979 & K210731.

Conclusion
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 IPS Forearm System has the same intended use, same principles of operation, and similar technological features compared to the predicate device and reference devices. Any differences in technological features between the subject and predicate devices do not raise different questions of safety and effectiveness. The non-clinical performance data presented supports substantial equivalence of KLS Martin IPS Forearm System to the predicate and reference devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Performance Data

Mechanical testing
In accordance with ASTM F382-24, static and dynamic 4-point bending tests were conducted to characterize the mechanical strength and durability of the worst-case KLS Martin IPS Forearm implant.

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

Conclusion

Mechanical testing
Static and dynamic four-point bending tests performed, in accordance with ASTM F382-24, on the worst-case IPS Forearm plate demonstrate that it meets all established acceptance criteria. Furthermore, the results confirm that the worst-case IPS Forearm plate outperforms the worst-case predicate IXOS plate.

MR Environment Safety Information
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 IPS Forearm Implants. 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 virtual human anatomy 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 IPS Forearm Implant portfolio can be safely scanned under the conditions presented in the labeling.