May 25, 2023

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

Re: K222624
Trade/Device Name: KLS Martin LINOS Wrist 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: April 25, 2023
Received: April 25, 2023

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 (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 located 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.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K222624

Device Name

KLS Martin LINOS Wrist System

Indications for Use *(Describe)*

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K222624

510(k) Summary

Prepared on: 2023-05-25

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	KLS-Martin L.P.
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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	liza.gordillo@klsmartin.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	KLS Martin LINOS Wrist System
Common Name	Plate, Fixation, Bone (primary); Screw, Fixation, Bone
Classification Name	Single/multiple component metallic bone fixation appliances and accessories (primary) Smooth or threaded metallic bone fixation fastener
Regulation Number	888.3030 (primary) / 888.3040
Product Code	HRS (primary) / HWC

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K142906	APTUS® Wrist 2.5 System	HRS
K171624	IXOS Radius Plate System (Reference Device)	HRS
K170124	KLS Martin Level One Hand Plating System (Reference Device)	HRS
K110 125	2.4 MM VA-LCP VOLAR RIM DISTAL RADIUS SYSTEM (Refere	HRS

K191412	VariAx 2 System, VariAx 2 Mini Fragment System (Reference De	HRS
K191972	ARIX Wrist System (Reference Device)	HRS

Device Description Summary

21 CFR 807.92(a)(4)

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)

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 intended use of the subject device is identical to the primary predicate device, APTUS® Wrist 2.5 System (K142906). 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 Predicates
The subject and predicate devices, as well as the reference devices, have the same fundamental technologies in that they are all designed for use in surgical procedures of the hand and forearm region and are manufactured in a variety of sizes and configurations to provide the physician with various sizing options to repair hand and forearm fractures, osteotomies, and arthrodeses.

Differences from Predicate
The subject device is manufactured from CP titanium (ASTM F67:2017) and Ti-6Al-4V (ASTM F136:2013), while the predicate device, K142906, is manufactured from CP titanium (ASTM F67:2017), the reference device, K171624, is made of CP titanium (ASTM F67:2017) and the reference device, K170124, is made of both CP titanium (ASTM F67:2017) and Ti-6Al-4V (ASTM F136:2013). Performance testing demonstrated that the differences in material does not affect the safety and effectiveness of the subject devices and can be determined substantially equivalent.

Conclusion
Based on the questions above as well as conformance to FDA-recognized standards, along with the performance data compared with the predicate, K142906, safety and effectiveness has been demonstrated.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Performance Data
Comparative head-to-head static and dynamic bench testing was conducted on the subject and predicate (Medartis AG APTUS Wrist 2.5 System (KI 42906)) devices to determine that the subject device has equivalent performance to the primary predicate. Additionally, comparative screw testing was performed to evaluate torsional strength, drive torque, and pullout strength in accordance with ASTM F543. Mechanical test results demonstrate that the KLS Martin LINOS Wrist System's performance is substantially equivalent to the primary predicate device. Biological safety risk assessments in compliance with ISO 10993-1 :2018 were completed on the subject devices and concluded the devices are biocompatible and appropriate for their intended use.

The gamma sterilization process for the sterile implants and instrumentation/accessories was validated in accordance with ISO 11137-1:2006 and ISO 11137-2:2012 using the VDmax25 method. The validation was also in accordance with ISO 11737-1:2018 and ISO 11737-2:2019. The dynamic-air-removal steam sterilization cycle parameters for the non-sterile implants and non-sterile instrumentation/accessories were validated in accordance with ISO 17665-1 :2006/(R)2013.
Shelf life for all gamma sterilized components is five (5) years from the date of sterilization.
LAL endotoxin testing was conducted to address the presence of bacterial endotoxins and ensure they meet pyrogen limit specifications in accordance with AAMI ANSI ST72: 2019.

Packaging validations were performed for the PETG blister pack with 1073B Tyvek cover in accordance with ISO 11607-1:2019, ISO 11607-2:2019, and ASTM D4169:2016

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

Conclusions
The KLS Martin LINOS Wrist System has the same intended use and similar technological characteristics as the predicate device and reference devices. Technological differences have been addressed through performance data from the predicate and reference devices, in addition to analysis of peer-reviewed clinical studies. All information provided show the safe and effective use of the subject device for the intended patient population.

In conclusion, the potential benefits associated with the use of the subject device outweigh its potential risks for the targeted patient population. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence.