September 17, 2024

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

Re: K233721
Trade/Device Name: KLS Martin Drill-Free MMF Screw
Regulation Number: 21 CFR 872.4880
Regulation Name: Intraosseous Fixation Screw Or Wire
Regulatory Class: Class II
Product Code: DZL
Dated: August 19, 2024
Received: August 19, 2024

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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K233721

Device Name

KLS Martin Drill-Free MMF Screw

Indications for Use *(Describe)*

The KLS Martin Drill-Free MMF Screw is indicated for temporary stabilization of mandibular and maxillary fractures to maintain proper occlusion during surgery in adults and adolescents (age 12 and older) in whom permanent teeth have erupted.

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) #: K233721

510(k) Summary

Prepared on: 2024-09-17

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	KLS-Martin L.P.
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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 Drill-Free MMF Screw
Common Name	Screw, Fixation, Intraosseous
Classification Name	Intraosseous fixation screw or wire
Regulation Number	872.4880
Product Code	DZL

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K083432	Drill Free MMF Screw	DZL
K231599	Stryker MMF Screw	DZL
K153482	KLS Martin Thoracic Plating System	HRS

Device Description Summary

21 CFR 807.92(a)(4)

The KLS Martin Drill-Free MMF Screw are bone-borne, self-drilling screws for maxillomandibular fixation (MMF). The screws are intended to provide stabilization of mandibular and maxillary fractures as well as maintain proper occlusion during intraoperative bone fixation. These screws may be applied prior to or after exposure of the fracture. The Drill Free MMF Screw is manufactured from stainless steel (ASTM F138) with a head designed with a hole to allow passing and securing ligature wire during the procedure and is available in threaded lengths of 2.0 x 8.0 mm - 2.0 x 12.0mm. Implants are available both sterile and non-sterile.

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

The KLS Martin Drill-Free MMF Screw is indicated for temporary stabilization of mandibular and maxillary fractures to maintain proper occlusion during surgery in adults and adolescents (age 12 and older) in whom permanent teeth have erupted.

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

The indications for use of the subject device, KLS Martin Drill Free MMF Screw, is identical to the primary predicate device, KLS Martin Drill Free MMF Screw (K083432). 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 device, KLS Martin Drill Free MMF Screw is substantially equivalent to the predicate device, Drill Free MMF Screw (K083432) with respect to intended use, design, materials, and manufacturing. Anatomical sites used for the subject and predicate device are identical.

The KLS Martin Drill Free MMF Screw is identical to the predicate device (K083432) in material, stainless steel (ASTM F138).

Differences from Predicate
The KLS Martin Thoracic Plating System (K153482) has been included as a reference device to support the difference in sterilization method between the KLS Martin Drill Free MMF Screw and predicate devices with regard to the addition of the sterile screws. The sterile screws will use the same sterilization method, same packaging, and the same sterile barrier shelf life as the reference device (K153482).

The Stryker MMF Screw (K231599) has been included as a reference device to support the change in labeling, expanding the intended patient population to include skeletally mature patients.

Conclusion
The sterile KLS Martin Drill Free MMF Screw has the same intended use, same principles of operation, and technological characteristics as the predicate devices. No new issues of safety or effectiveness have been raised.

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 (KLS Martin Drill Free MMF Screw (K083432)) 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 F543-23. Mechanical test results demonstrate that KLS Martin MMF Screw's performance is substantially equivalent to the primary predicate device. Biological safety risk assessments in compliance with ISO 10993-1:2018 concluded the devices are biocompatible and appropriate for their intended use. LAL endotoxin testing was conducted to address the presence of bacterial endotoxins and ensure they meet pyrogen limit specifications in accordance with ANSI/AAMI ST72:2019.

The gamma sterilization process for the sterile implants was validated in accordance with ISO 11137-1:2015 and ISO 11137-2:2015 using the VDmax25 method. The validation was also performed in accordance with ISO 11737-1:2018 and ISO 11737-2:2019.

Packaging validations were performed for the PETG blister pack with 1073B Tyvek cover in accordance with ISO 11607-1 and ASTM D7386.

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

Conclusions
The KLS Martin Drill-Free MMF Screw 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.

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.