November 22, 2019

KLS-Martin L.P.
Katie Rutland
Senior Regulatory Affairs Specialist
11201 Saint Johns Industrial Parkway S
Jacksonville, Florida 32246

Re: K191028
Trade/Device Name: KLS Martin Individual Patient Solutions
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: October 24, 2019
Received: October 25, 2019

Dear Katie Rutland:

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,

for Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191028

Device Name

KLS Martin Individual Patient Solutions

Indications for Use *(Describe)*

KLS Martin Individual Patient Solutions implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions.

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.

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K191028

510(k) Summary

21 CFR 807.92

Submitter:	KLS-Martin L.P. 11201 Saint Johns Industrial Pkwy S Jacksonville, FL 32246
Contact Person:	Katie Rutland Senior Regulatory Affairs Specialist Phone: 800-625-1557 Email: katie.rutland@klsmartinusa.com
Date Prepared:	November 21, 2019
Trade Name:	KLS Martin Individual Patient Solutions
Common Name:	Plate, Bone
Classification Name:	Bone plate
Regulatory Class:	II
Product Code:	JEY
Regulation Number:	21 CFR 872.4760
Primary Predicate:	KLS Martin Individual Patient Solutions **(K163579)**
Reference Devices:	TruMatch CMF Titanium 3D Printed Implant **(K173039)** KLS Martin Micro Osteosynthesis System **(K944565)** KLS Martin IPS Planning System **(K182789)**

Device Description:

KLS Martin Individual Patient Solutions is comprised of patient-specific models and metallic bone plates used in conjunction with metallic bone screws for internal fixation of maxillofacial / midface and mandibular bones. The devices are manufactured based on medical imaging (CT scan) of the patient's anatomy with input from the physician during virtual planning and prior to finalization and production of the device. The physician only 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 adequate fit.

Implants are provided non-sterile, range in thickness from 0.3 mm – 10 mm, and are manufactured using traditional (subtractive) methods from either CP Titanium (ASTM F67)

or Ti-6Al-4V (ASTM F136) materials or additive methods from Ti-6Al-4V. These patient-specific devices are fixated with previously cleared KLS Martin screws.

Indications for Use: KLS Martin Individual Patient Solutions implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions.

Technological Characteristics & Substantial Equivalence Discussion

The intended use of the subject device, KLS Martin Individual Patient Solutions, is the same as the KLS Martin primary predicate device, KLS Martin Individual Patient Solutions (K163579), differing mainly in the skeletal region for which they are intended and technological specifications. The potential impact on substantial equivalence of each technological difference was addressed through risk analysis and verification and validation testing.

Similarities to Predicate

The subject and primary predicate devices are both intended for reconstructive surgery in the facial skeleton and share the same fundamental principles of operation – patient-specific metallic bone plates used in conjunction with metallic bone screws for facial reconstructive surgery.

Both the subject and predicate devices use image data obtained from medical scanners, such as a CT scan. They both use validated commercially off-the-shelf (COTS) software applications to transfer patient imaging from a DICOM format to a .STL format and manipulate the images to produce a final design file.

The manufacturing materials used in the subject device are identical to those cleared in KLS Martin Individual Patient Solutions (K163579). The design and dimensions of the plates are based on patient-specific data, using identical methods described in K163579, manufactured from either CP Titanium (ASTM F67) or Ti-6Al-4V (ASTM F136) using traditional (subtractive) or additive manufacturing (Selective Laser Melting (SLM)) methods.

The specifications for the subject, primary predicate, and reference devices are similar with respect to plate style, width, length, degree of curvature, fixation hole spacing, and number of fixation holes. Mechanical bench testing performed on both a worst-case midface and orbital plate design, demonstrate that the design expansion to include orbital and maxillofacial / midface implants does not impact substantial equivalence.

All subject and predicate devices are provided non-sterile and require the end-user to process the devices using validated cleaning and sterilization methods prior to use as recommended in the device labeling.

Differences from Predicate

The indications for use statement for the subject device of this submission differs from the primary predicate in the addition of the maxillofacial / midface skeletal regions. The skeleton region for which the predicate device was cleared includes only the mandibular region. The subject device expands the indications for use by including the maxillofacial / midface skeletal region and add these devices to the KLS Martin Individual Patient Solutions implant devices. The change in skeletal region presented in the indications for use statement of the subject device compared to the primary predicate device does not impact the substantial

equivalence of the subject device. This difference in skeletal region is mitigated by previously cleared reference devices that are intended for the maxillofacial / midface regions.

The subject and primary predicate devices use the same validated commercially off-the-shelf (COTS) software applications to transfer patient imaging from a DICOM format to a .STL format, Materialise Mimics and Geomagic® Freeform Plus™. However, the subject device utilizes an additional COTS software for designing orthognathic implants, IPS CaseDesigner. IPS CaseDesigner was cleared under K161634. This software was also utilized and reviewed in the reference device, K182789, in the creation of orthognathic splints.

Previously cleared specifications for the predicate plate thicknesses range from 1.0 mm –3.0 mm and are fixated with previously cleared KLS Martin titanium screws ranging in diameter from 2.0 mm – 3.2 mm in lengths from 5 mm – 22 mm. The subject device plates range in thickness from 0.3 mm – 10 mm and are fixated with previously cleared KLS Martin titanium screws ranging in diameter from 1.5 mm – 3.2 mm in lengths from 3.5 mm – 22 mm. The subject device dimensions differ by offering additional device sizes to accommodate cases in orbital and maxillofacial / midface reconstruction. Subject device implants with thicknesses ranging from 0.6 mm – 10 mm will be used in maxillofacial reconstructive surgeries involving volumetric defects. Responsible clinical conditions for volumetric defects include, but are not limited to, bone resection due to tumors or disease, blunt force trauma, facial defects, bone atrophy, and aesthetic augmentation for facial symmetry. The differences in plate thickness between the subject and predicate devices are addressed with performance data and previously cleared reference devices with plate dimensions that align with the subject device specifications.

Reference Devices

TruMatch CMF Titanium 3D Printed Implant (K173039) has been included as a reference device to address the technological differences between the primary predicate and subject device. The subject device is expanding the primary predicate anatomical regions from the mandible to the orbital and maxillofacial / midface skeletal regions. Both the reference and subject devices offer volumetric implants that augment and contour in the midface skeletal region to allow facial aesthetics and symmetry reconstruction. The reference device is included for the maxillofacial / midface plate design specifications that fall outside of the primary predicate specifications for volumetric implants in the subject device to aid in facial aesthetics and the creations of symmetry in reconstructive surgeries. TruMatch devices are cleared for orbital plate thicknesses ranging from 0.4 mm – 1.5 mm and midface plate thicknesses ranging from 0.8 mm – 10 mm.

The KLS-Martin Mini Osteosynthesis System (K944565) has been included as a reference device to address the technological differences between the primary predicate and subject device. The subject device includes implants for the orbital region with a minimum thickness of 0.3 mm, and implants for the midface region with a minimum thickness of 0.6 mm. Because the primary predicate only includes devices for the mandible region with a minimum thickness of 1.0 mm, and the TruMatch CMF Titanium 3D Printed Implant reference device only includes implants with minimum thicknesses of 0.4 mm and 0.8 mm for the orbital and midface regions, respectively, K944565 reference devices have been included to address the subject device minimum plate thicknesses of 0.3 mm – 0.6 mm. The K944565 reference device includes traditionally manufactured (subtractive, milled) titanium plates of various sizes and shapes that range in thickness from 0.3 – 0.6 mm and are intended

for the stabilization of bone in oral-maxillo-craniofacial surgery. Comparative performance testing and additional bench analysis has addressed any minor differences between the subject, primary predicate, and reference devices.

The KLS Martin IPS Planning System (K182789) has been included as a reference device to support compatibility with the subject device.

A device comparison table of the subject, predicate, and reference devices is provided below.

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	KLS Martin Individual Patient Solutions	**KLS Martin Individual Patient Solutions K163579**	**TruMatch CMF Titanium 3D Printed Implant K173039**	**KLS Martin Micro Osteosynthesis System (1.5mm) K944565**	**KLS Martin IPS Planning System K182789**
	(Subject Device)	**(Primary Predicate)**	**(Reference Device)**	**(Reference Device)**	**(Reference Device)**
Indications for Use	KLS Martin Individual Patient Solutions implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions.	KLS Martin Individual Patient Solutions implant devices are intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.	The TruMatch CMF Titanium 3D Printed Implant is a patient specific implant and is intended for bone fixation and reconstruction, restoration of bone defects and intended to provide continuity in regions where the bone is missing and/or to augment the bone by means of an onlay device in the maxillofacial skeleton, midface and chin.	The KLS Martin Micro Osteosynthesis System (1.5mm) is used in oral-maxillo-cranio-facial surgery to stabilize fractured bone structures. The bone segments are attached to the plate with screws to prevent movement of the screws.	The KLS Martin Individual Patient Solutions (IPS) Planning System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the IPS Planning System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, guides, splints, and case reports for use in maxillofacial surgery. The IPS Planning System is also intended as a pre-operative software tool for simulating/ evaluating surgical treatment options.

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	KLS Martin Individual Patient Solutions	**KLS Martin Individual Patient Solutions K163579**	**TruMatch CMF Titanium 3D Printed Implant K173039**	**KLS Martin Micro Osteosynthesis System (1.5mm) K944565**	**KLS Martin IPS Planning System K182789**
	(Subject Device)	**(Primary Predicate)**	**(Reference Device)**	**(Reference Device)**	**(Reference Device)**
Patient-specific?	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.	No.	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.
Classification	21 CFR 872.4760, Class II	21 CFR 872.4760, Class II	21 CFR 872.4760, Class II	21 CFR 872.4760, Class II	21 CFR 872.4120, Class II 21 CFR 892.2050, Class II
Product Code	JEY	JEY	JEY	JEY	DZJ, LLZ
Material	Anatomical Models: Epoxy/Acrylic Resins Implants: CP Titanium or Ti-6Al-4V	Anatomical Models: Epoxy/Acrylic Resins Implants: CP Titanium or Ti-6Al-4V	Implants: CP Titanium	Implants: CP Titanium & Ti-6Al-4V	Anatomical Models: Epoxy/Acrylic Resins Cutting/Marking Guides: Polyamide, Ti-6Al-4V, CP Titanium Splints: acrylic/methacrylic resins
Manufacturing Method	Epoxy/Acrylic Resins: Stereolithography (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: Traditional and 3D (Additive; Selective Laser Melting)	Epoxy/Acrylic Resins: Stereolithography (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; Selective Laser Melting)	CP Titanium: 3D Additive	Subtractive (traditional) - Milling	Epoxy/Acrylic Resins: Stereolithography (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; Selective Laser Melting) Polyamide: 3D (Additive; Selective Laser Sintering)
Sterilization	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)
Anatomical Sites	Maxillofacial / Midface & Mandible	Mandible	Maxillofacial / Midface & Chin	Craniomaxillofacial	Maxillofacial / Mandible

	KLS Martin Individual Patient Solutions	**KLS Martin Individual Patient Solutions K163579**	**TruMatch CMF Titanium 3D Printed Implant K173039**	**KLS Martin Micro Osteosynthesis System (1.5mm) K944565**	**KLS Martin IPS Planning System K182789**
	(Subject Device)	**(Primary Predicate)**	**(Reference Device)**	**(Reference Device)**	**(Reference Device)**
Plate Specifications					
Thickness	• Orbital: 0.3 mm – 1.0 mm • Maxillofacial / midface reconstruction: o 0.6 mm – 10 mm • Mandibular reconstruction: 1.0 mm – 3.0 mm	Mandibular reconstruction: 1.0 mm – 3.0 mm	• Orbital: 0.4 mm – 1.5 mm • Midface reconstruction: o 0.8 mm – 10 mm • Mandibular reconstruction: 1.2 mm – 10 mm	0.3 mm – 0.6 mm	Not applicable
Style	Non-compression Compression Threaded	Non-compression Compression Threaded	Mesh-Shaped	Standard Non-locking	Not applicable
Width (screw-hole dependent)	Maxillofacial / midface: Min: ≥ 4.5 mm (around screw holes) Min: ≥ 3 mm (not around screw hole) Max: Dependent on screw-hole Mandibular: Same as predicate	Min: 7 mm Max: 8.5 mm	Unknown	Not applicable	Not applicable
Length	Maxillofacial / midface: Min: 18 mm Max: 350 mm Mandibular: Same as predicate	Min: 31 mm Max: 320 mm	Min: 10 mm Max: 294 mm	Not applicable	Not applicable
Degree of curvature (in-plane)	Maxillofacial / midface	Min: 90° Max: 180°	Unknown	Not applicable	Not applicable

	KLS Martin Individual Patient Solutions	KLS Martin Individual Patient Solutions K163579	TruMatch CMF Titanium 3D Printed Implant K173039	KLS Martin Micro Osteosynthesis System (1.5mm) K944565	KLS Martin IPS Planning System K182789
	(Subject Device)	**(Primary Predicate)**	**(Reference Device)**	**(Reference Device)**	**(Reference Device)**
	Min: 30° Max: 180° Mandibular: Same as predicate				
Degree of curvature (out-of- plane)	Maxillofacial / midface: Min: 15° Max: 180° Mandibular: Same as predicate	Min: 60° Max: 180°	Unknown	Not applicable	Not applicable
Hole spacing	Orbital & Maxillofacial / midface: ≥4.5 mm Mandibular: Same as predicate	≥ 8 mm	Unknown	Not applicable	Not applicable
Number of Holes	Orbital & Maxillofacial / midface: Min: ≥ 2 per side of defect Max: Dependent on length & hole spacing Mandibular: Same as predicate	Min: 4 Max: Dependent on length & hole spacing	Unknown	Not applicable	Not applicable
Screw Diameter	Orbital 1.5 mm Maxillofacial / midface 1.5 mm – 2.3 mm Mandibular: Same as predicate	2.0 mm – 3.2 mm	Unknown	1.5 mm – 1.8 mm	1.5 mm – 2.7 mm
Screw Length	Orbital & Maxillofacial / midface	5 mm – 22 mm	Unknown	3.5 mm – 15 mm	4 mm – 22 mm

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	(Subject Device)	**(Primary Predicate)**	**(Reference Device)**	**(Reference Device)**	**(Reference Device)**
	3.5 mm – 22 mm Mandibular: Same as predicate				
Screw Style	maxDrive & crossDrive (Drill-Free, locking [ThreadLock Taper Screw -TLTS], standard)	maxDrive & crossDrive (Drill-Free, locking [ThreadLock Taper Screw -TLTS], standard)	Unknown	Centre-Drive	maxDrive & crossDrive (Drill-Free, locking [ThreadLock Taper Screw -TLTS])

Performance Testing – Non-clinical

Tensile & Bending Testing

Bench testing was used to demonstrate that any differences between the subject, primary predicate, and reference devices do not negatively impact substantial equivalence. Mechanical testing was conducted in accordance with ASTM F382 to compare the bending properties of the subject plates against plates previously cleared in reference device K944565. The bending resistance and fatigue life of the subject devices was determined to be substantially equivalent to the K944565 plates.

Biocompatibility Testing

Biocompatibility endpoints were evaluated in accordance with ISO 10993-1. The battery of cytotoxicity, chemical analysis, sensitization and irritation, and chemical/material characterization testing was leveraged from K163579 for titanium devices. The subject devices are identical to the primary predicate devices in material formulations, manufacturing methods and processes, and sterilization methods. No other chemicals have been added (e.g., fillers, additives, cleaning agents). Therefore, this adequately addresses biocompatibility for the subject device system.

Sterilization Testing

Steam sterilization validations were performed using the dynamic-air-removal cycle in accordance with ISO 17665-1:2006 to a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method. All test method acceptance criteria were met. Validations for devices manufactured from titanium were leveraged from the predicate device, KLS Martin Individual Patient Solutions (K163579). Subject titanium devices are identical in formulation, manufacturing processes, and post-processing procedures (cleaning & sterilization) as the predicate device.

Pyrogenicity Testing

LAL endotoxin testing was conducted according to AAMI ANSI ST72 to address the presence of bacterial endotoxins and ensure they meet pyrogen limit specifications. The results of the testing demonstrate that the subject devices contain endotoxin levels below the USP allowed limit for medical devices and meet pyrogen limit specifications. LAL endotoxin testing for titanium was leveraged from the predicate device, KLS Martin Individual Patient Solutions (K163579). Subject titanium devices are identical in formulation, manufacturing processes, and post-processing procedures (cleaning & sterilization) as the predicate device.

Software Verification and Validation

Software verification and validation was performed on each individual software application that is used in the planning and design of the patient's images (CT). Quality and on-site user acceptance testing provide objective evidence that all software requirements and specifications were implemented correctly and completely and are traceable to system requirements. Testing required as a result of risk analysis and impact assessments showed conformity with pre-defined specifications and acceptance criteria. Software documentation demonstrates all appropriate steps have been taken to ensure mitigation of any potential risks and performs as intended based on the user requirements and specifications.

Performance Testing – Clinical

Clinical testing was not necessary for the substantial equivalence determination.

Substantial Equivalence Conclusion

KLS Martin Individual Patient Solutions has the same intended use and similar technological characteristics as the primary predicate device. Technological differences have been assessed through performance testing and inclusion of reference devices presented in this submission. Testing and the incorporation of reference devices with similar technological characteristics as the subject device have demonstrated that any differences in technological characteristics between the subject device and primary predicate device do not impact substantial equivalence.