KLS-Martin L.P.
Pam Martin
Regulatory Affairs Project Management
11201 Saint Johns Industrial PKWY S
Jacksonville, Florida 32246

7/18/2022

Re: K210731
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, DZJ, LLZ
Dated: June 27, 2022
Received: June 28, 2022

Dear Pam Martin:

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210731

Device Name

KLS Martin Individual Patient Solutions

Indications for Use *(Describe)*

KLS Martin Individual Patient Solutions (IPS) is intended as a pre-operative software tool for simulating / evaluating surgical treatment options as a software 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 software and the result is an output data file that may then be provided as digital models or used as input in an additive manufacturing portion of the system that produces physical outputs including implants, anatomical models, guides, splints, and case reports for use in maxillofacial, midface, & mandibular surgery.

KLS Martin Individual Patient Solutions (IPS) implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions in children (2 years of age to < 12 years of age), adolescents (12 years of age - 21 years of age), and adults.

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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K210731
510(k) Summary
21 CFR 807.92

Submitter:	KLS-Martin L.P. 11201 Saint Johns Industrial Pkwy S. Jacksonville, FL 32246
Primary Contact:	Pam Martin, MSc, RAC Regulatory Affairs Project Manager Phone: 800-625-1557 Email: pmartin@klsmartin.com
Alternate Contact:	Melissa Bachorski Director of RA/QMS North America Phone: 800-625-1557 Email: melissa.bachorski@klsmartin.com
Date Prepared:	July 15, 2022
Trade Name:	KLS Martin Individual Patient Solutions
Common Name:	System used to plan & fabricate patient-specific bone plates, anatomical models, cutting/marking guides, splints, and case reports
Regulation Numbers:	21 CFR 872.4760
Regulatory Class:	II
Primary ProCode:	JEY
Subsequent ProCodes:	DZJ, LLZ
Primary Predicate:	KLS Martin Individual Patient Solutions **(K191028)**
Reference Devices:	KLS Martin Mini Osteosynthesis System **(K943347)** TruMatch CMF Titanium 3D Printed Implant **(K170272)** KLS Martin IPS Planning System **(K182789)**

Device Description:

KLS Martin Individual Patient Solutions (IPS) is comprised of a collection of software and associated additive manufacturing equipment intended to produce various outputs to support reconstructive and orthognathic surgeries. The system processes the medical images to produce various patient-specific physical and/or digital output devices which include implants, anatomical models, guides, splints, and case reports.

Patient-specific metallic bone plates are 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 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

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the generated output device over a 3D model of the patient's anatomy to ensure its dimensional properties allow an adequate fit.

Implants are provided non-sterile and are manufactured using traditional (subtractive) or additive manufacturing methods from either CP Titanium (ASTM F67) or Ti-6Al-4V (ASTM F136). These patient-specific devices are fixated with previously cleared KLS Martin screws.

Indications for Use:

KLS Martin Individual Patient Solutions (IPS) is intended as a pre-operative software tool for simulating / evaluating surgical treatment options as a software 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 software and the result is an output data file that may then be provided as digital models or used as input in an additive manufacturing portion of the system that produces physical outputs including implants, anatomical models, guides, splints, and case reports for use in maxillofacial, midface, & mandibular surgery.

KLS Martin Individual Patient Solutions (IPS) implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions in children (2 years of age to < 12 years of age), adolescents (12 years of age – 21 years of age), and adults.

Technological Characteristics & Substantial Equivalence Discussion:

The intended use of the subject device is identical to the primary predicate device, KLS Martin Individual Patient Solutions (K191028). The subject device differs from the primary predicate mainly in the target patient population 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 & Reference Devices

The subject and predicate devices are intended for reconstructive surgery in the facial skeleton and share the same fundamental principles of operation – Software is used to convert individual patient CT scans to digital models for subsequent surgical planning & fabrication of patient-specific devices for use in facial reconstructive surgery.

The subject and predicate devices utilize image data obtained from a CT scan, which is input into validated commercially off-the-shelf (COTS) software applications to transfer patient imaging from DICOM to. STL format and manipulate the images to produce a final design file.

The subject devices are manufactured using identical methods and materials to those cleared in the primary predicate (K191028) and reference device (K182789), with the exception of the new splint material presented in this submission. The new splint material is discussed below in *Splints.*

Both systems utilize additive manufacturing methods to produce physical output devices that include patient-specific implants, anatomical models, guides, and splints. In addition, the systems produce digital models and case reports for the physician to use for planning of maxillofacial surgeries or to use during surgery.

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Materials used in the manufacture of the subject output devices are synthetic polymers, acrylic resins, and titanium (CP titanium & Titanium Alloy), which are identical to what was evaluated in the primary predicate device, K191028.

The specifications for the subject device implants are similar to predicate K191028 with respect to plate style, thickness, width, length, degree of curvature, fixation hole spacing, and number of fixation holes. The titanium screws used to fixate the subject device plates range in diameter from 1.5 mm – 3.2 mm in lengths from 3.5 mm – 22 mm, which are identical to the screws previously evaluated in K191028.

The 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 & Reference Devices

Components & Indications for Use

The primary predicate components include the planning software, implants, and anatomical models. The reference device (K182789) components include the planning software, anatomical models, cutting/marking guides, splints, and case reports. The subject device system combines all previously cleared components and indications for use into one system – planning software, implants, anatomical models, cutting/marking guides, splints, and case reports.

Target Population

The primary predicate device, K191028, was cleared for the adult population. The purpose of this submission is to expand the patient population to include the following pediatric subpopulations:

- Children (2 years of age to < 12 years of age)
- Adolescents (12 years of age – 21 years of age)

A risk assessment has been performed based on FDA guidance, "*Premarket Assessment of Pediatric Medical Devices*, March 24, 2014" for these subpopulations with supporting peer-reviewed clinical literature to demonstrate the safety and effectiveness of the subject device implants for use in the target pediatric subpopulations.

The reference device, K182789, was previously cleared for all pediatric subpopulations from neonate through adolescent to adult for all IPS components with the exception of permanent implants. The TruMatch CMF Titanium 3D Printed Implant (K170272) has been included as a reference device to support the use of permanent implants in the adolescent population.

Specifications

The subject device dimensions differ from the predicate by offering additional device sizes to accommodate volumetric defects in facial reconstruction cases for the mandible. Previously cleared specifications for the K191028 predicate plate thickness for the mandibular region ranges from 1.0 mm – 3.0 mm. The subject device plates for the mandibular region differ by ranging in maximum thickness up to 10 mm. This expansion of the design envelope thickness for mandibular implants is supported by our previously cleared primary predicate maxillofacial / midface devices that were cleared for up to 10 mm in maximum thickness to accommodate volumetric defects.

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The subject device also proposes two mandibular implant categories with distinct specifications based on type of mandible defect, continuity vs. non-continuity. Minimum thickness for mandible (non-continuity) & maxilla/midface defects is 0.6 mm and 2.0 mm for mandible continuity defects. Minimum thickness for orbital reconstruction is 0.3 mm.

Mandible continuity defects are known to produce larger loads than non-continuity defects or maxillary implants, which is demonstrated by the larger reference device specifications in that situation. Maxillary defects are not subjected to the same loads and thus, subject devices in this area are not designed for dental loading unless supported by bone. Orbital implants are non-load bearing, other than supporting intraorbital contents.

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.

Previously defined specifications for orbital implants in the K191028 predicate were limited to implant thickness, hole spacing, and number of holes. Additional specifications (width, length, and degree of curvature) have been defined for the subject devices in the orbital region to formulate a realistic worst-case construct, provide better control on design variations, and to parallel specifications for the midface and mandible regions. These new specification categories are more restrictive than in the K191028 predicate device and therefore, result in more controllable and mechanically stable design variations.

Any differences in specifications between the subject and predicate devices have been addressed with mechanical bench testing performed on the new worst-case midface, orbit, and mandible plate designs to demonstrate that the design expansion does not raise new or different questions for the determination for substantial equivalence. The K943347 reference device includes traditionally manufactured (subtractive, milled) titanium plates of various sizes and shapes that range in thickness from 0.6 – 1.0 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.

Splints

The subject device system includes splints additively manufactured from Ti-6Al-4V (ASTM F136:2013) via SLM methods. The subject device also includes splints additively manufactured from a light-cured resin photopolymer material. The photopolymer resin is composed of acrylate/methacrylate polymers and is manufactured using cDLM methods, which is similar in material composition and uses similar manufacturing methods as the acrylic/methacrylic resins used to fabricate splints from DLP methods previously evaluated under reference device K182789.

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 K191028**	**KLS Martin IPS Planning System K182789**	**KLS Martin Mini Osteosynthesis System (2.0mm) K943347**	**TruMatch CMF Titanium 3D Printed Implant System K170272**
	(Subject Device)	**(Primary Predicate)**	**(Reference Device)**	**(Reference Device)**	**(Reference Device)**
Indications for Use	KLS Martin Individual Patient Solutions (IPS) is intended as a pre-operative software tool for simulating / evaluating surgical treatment options as a software 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 software and the result is an output data file that may then be provided as digital models or used as input in an additive manufacturing portion of the system that produces physical outputs including implants, anatomical models, guides, splints, and case reports for use in maxillofacial, midface, & mandibular surgery. KLS Martin Individual Patient Solutions (IPS) implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions in children (2 years of age to < 12 years of age), adolescents (12 years of age - 21 years of age), and adults.	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.	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.	The KLS Martin Mini Osteosynthesis System is intended for use in the stabilization and fixation of mandibular fractures and oral-maxilla-cranio-facial surgery. The bone segments are attached to the plate with screws to prevent movement of the segments.	The TruMatch CMF Titanium 3D Printed Implant System is intended for bone fixation, positioning and reconstruction of the maxillofacial skeleton, midface, mandible and chin in adolescents (greater than 12 to 21 years of age) and adults. Specific indications for use: • Orthognathic surgery • Reconstructive mandible and maxillofacial surgery • Mandible and maxillofacial trauma surgery
Patient-specific?	Yes, manufactured based on patient CT scan	Yes, manufactured based on patient CT scan	Yes, manufactured based on patient CT scan	No.	Yes, manufactured based on patient CT scan
Classification	21 CFR 872.4760, Class II	21 CFR 872.4760, Class II	21 CFR 872.4120, Class II 21 CFR 892.2050, Class II	21 CFR 872.4760, Class II	21 CFR 872.4760, Class II
Product Code	JEY, DZJ, LLZ	JEY	DZJ, LLZ	JEY	JEY
Anatomical Sites	Maxillofacial / Midface & Mandible	Maxillofacial / Midface & Mandible	Maxillofacial / Midface & Mandible	Craniomaxillofacial	Maxillofacial / Midface, Mandible & Chin

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	(Subject Device)	**(Primary Predicate)**	**(Reference Device)**	**(Reference Device)**	**(Reference Device)**
Material	• Anatomical Models: Epoxy/Acrylic Resins • Implants: CP Titanium or Ti-6Al-4V • Cutting/Marking Guides: Polyamide, Ti-6Al-4V, CP Titanium • Splints: acrylic/methacrylic/photopolymer resins, Ti-6Al-4V	• Anatomical Models: Epoxy/Acrylic Resins • Implants: CP Titanium or Ti-6Al-4V	• Anatomical Models: Epoxy/Acrylic Resins • Cutting/Marking Guides: Polyamide, Ti-6Al-4V, CP Titanium • Splints: acrylic/methacrylic resins	• Implants: CP Titanium or Ti-6Al-4V	• Implants: CP Titanium
Manufacturing Method	• Epoxy/Acrylic Resins: Additive; Stereolithography (SLA) • CP Titanium: Traditional (Subtractive) • Ti-6Al-4V: Additive; Selective Laser Melting (SLM) & Traditional (Subtractive) • Acrylic/methacrylic resins (DLP) • Photopolymer resins (cDLM)	• Epoxy/Acrylic Resins: Additive; Stereolithography (SLA) • CP Titanium: Traditional (Subtractive) • Ti-6Al-4V: Additive; Selective Laser Melting (SLM) & Traditional (Subtractive)	• Epoxy/Acrylic Resins: Additive; Stereolithography (SLA) • CP Titanium: Traditional (Subtractive) • Ti-6Al-4V: Additive; Selective Laser Melting (SLM) • Polyamide: Additive; Selective Laser Sintering (SLS) • Acrylic/methacrylic resins (DLP)	• Traditional (Subtractive – Milling)	• CP Titanium: 3D Additive
Sterilization	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)
Target Population	• Children (2 years of age to < 12 years of age) • Adolescents (12 years of age – 21 years of age) • Adults	• Adults	• Neonates (birth to 28 days) • Infants (29 days to < 2 years of age • Children (2 years of age to < 12 years of age) • Adolescents (12 years of age – 21 years of age) • Adults	• Not specified	• Adolescents (12 years of age – 21 years of age) • Adults

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	(Subject Device)	**(Primary Predicate)**	**(Reference Device)**	**(Reference Device)**	**(Reference Device)**

Thickness	• Orbital: 0.3 mm – 1.0 mm
	• Maxillofacial / midface reconstruction: 0.6 mm – 10 mm
	• Mandibular reconstruction:
	  ○ 0.6 mm – 10 mm (Non-continuity defects)
	  ○ 2.0 mm – 10 mm (Continuity defects)
		• Orbital: 0.3 mm – 1.0 mm
		• Maxillofacial / midface reconstruction:
		  ○ 0.6 mm – 10 mm
		• Mandibular reconstruction:
		  ○ 1.0 mm – 3.0 mm
			Not applicable	• 0.6 mm – 1.0 mm	Orthognathic applications:
					• Maxillary fixation: 0.8 mm – 1.5 mm
					• Mandibular fixation BSSO: 1 – 1.5 mm
					• Mandibular fixation genioplasty: 0.8 mm – 1.5 mm
					Reconstruction applications: Orbit
					• Orbital fracture treatment: 0.8 mm – 1.2 mm
					Reconstruction applications: Mandible, Midface
					• Mandibular reconstruction (small) / mandibular bone fixation: 1.5 mm – 2 mm
					• Mandibular reconstruction (large) / mandibular bone fixation and mandibular reconstruction with bone grafts: 2 mm – 3 mm
					• Midface reconstruction: 0.8 mm – 1.5 mm

Style	Non-compression Compression Threaded	Non-compression Compression Threaded	Not applicable	Standard Low profile	Multiple / various range of shapes
Width (Screw-hole dependent)	Orbit: Min: ≥ 3.5 mm (around screw holes) Min: ≥ 2.2 mm (not around screw hole) Maxillofacial / midface: Min: ≥ 4.5 mm (around screw holes) Min: ≥ 2.2 mm (not around screw hole) Mandibular (continuity defect): Min: ≥ 6.4 mm (around screw holes) Min: ≥ 3.2 mm (not around screw hole) Mandibular (non-continuity defect): Min: ≥ 4.5 mm (around screw holes) Min: ≥ 2.2 mm (not around screw hole)	Maxillofacial / midface: Min: ≥ 4.5 mm (around screw holes) Min: ≥ 3 mm (not around screw hole) Max: Screw-hole dependent Mandibular: Min: 7 mm Max: 8.5 mm	Not applicable	Not applicable	Unknown

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	(Subject Device)	**(Primary Predicate)**	**(Reference Device)**	**(Reference Device)**	**(Reference Device)**
Length	Orbit: Min: 10.5 mm Max: 50 mm Maxillofacial / midface: Min 18 mm Max: 350 mm Mandibular (continuity defect): Min: 25 mm Max: 350 mm Mandibular (non-continuity defect): Min: 18 mm Max: 350 mm	Maxillofacial / midface: Min: 18 mm Max: 350 mm Mandibular: Min: 31 mm Max: 320 mm	Not applicable	Not applicable	Min: 20 mm Max: 294 mm
Degree of curvature (In-plane)	Orbital, Mandibular, Maxillofacial / Midface: Min: 30° Max: 180°	Maxillofacial / midface: Min: 30° Max: 180° Mandibular: Min: 90° Max: 180°	Not applicable	Not applicable	Unknown
Degree of curvature (Out-of- plane)	Orbital, Mandibular, Maxillofacial / Midface: Min: 15° Max: 180°	Maxillofacial / midface: Min: 15° Max: 180° Mandibular: Min: 60° Max: 180°	Not applicable	Not applicable	Unknown
Hole spacing	Orbit: ≥3.5 mm Maxillofacial / midface: ≥4.5 mm Mandibular: ≥4.5 mm (non-continuity defect) ≥6.4 mm (continuity defect)	Orbital & Maxillofacial / midface: ≥4.5 mm Mandibular: ≥8 mm	Not applicable	Not applicable	Unknown

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	KLS Martin Individual Patient Solutions	**KLS Martin Individual Patient Solutions K191028**	**KLS Martin IPS Planning System K182789**	**KLS Martin Mini Osteosynthesis System (2.0mm) K943347**	**TruMatch CMF Titanium 3D Printed Implant System K170272**
	(Subject Device)	**(Primary Predicate)**	**(Reference Device)**	**(Reference Device)**	**(Reference Device)**
Number of Holes	Orbital, Mandibular, Maxillofacial / Midface: ≥2 per side of defect	Orbital & Maxillofacial / midface: Min: ≥ 2 per side of defect Max: Dependent on length & design Mandibular: Min: 4 Max: Dependent on length & design	Not applicable	Not applicable	Unknown
Screw Diameter	Orbital: 1.5 mm Maxillofacial / midface: 1.5 mm – 2.3 mm Mandibular: 2.0 mm – 3.2 mm	Orbital: 1.5 mm Maxillofacial / midface: 1.5 mm – 2.3 mm Mandibular: 2.0 mm – 3.2 mm	1.5 mm – 2.7 mm	1.5 mm – 2.3 mm	Unknown
Screw Length	Orbital & Maxillofacial / midface: 3.5 mm – 22 mm Mandibular: 5 mm – 22 mm	Orbital & Maxillofacial / midface: 3.5 mm – 22 mm Mandibular: 5 mm – 22 mm	4 mm – 22 mm	4 mm – 19 mm	Unknown
Screw Style	Head style: • maxDrive • crossDrive Design features: • Drill-Free • Locking • ThreadLock TaperScrew – TLTS • Standard	Head style: • maxDrive • crossDrive Design features: • Drill-Free • Locking • ThreadLock TaperScrew – TLTS • Standard	Head style: • maxDrive • crossDrive Design features: • Drill-Free • Locking • ThreadLock TaperScrew – TLTS • Standard	Head style: • Centre-Drive • maxDrive • crossDrive	Unknown

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Performance Data – Non-clinical

Tensile & Bending Testing

Bench testing was used to demonstrate that any dimensional or design differences between the subject, primary predicate, and reference devices do not raise new or different questions to determine 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 the reference device K943347. The bending resistance and fatigue life of the subject devices was determined to be substantially equivalent to the K943347 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 K191028 for titanium devices. The battery of cytotoxicity, sensitization and irritation, and chemical/material characterization testing was leveraged from K182789 for devices made from previously evaluated synthetic polymers and acrylic resins.

The subject device also includes splints additively manufactured from a light-cured photopolymer resin material composed of acrylate/methacrylate polymers. The battery of cytotoxicity, sensitization and irritation, and material mediated pyrogenicity testing provided in this submission adequately addresses the necessary biocompatibility endpoints per ISO 10993.

The subject device's manufacturing methods and processes are similar to the predicate device. 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 additively manufactured from titanium were leveraged from the primary predicate device, K191028. Validations for devices manufactured from previously evaluated synthetic polymers and acrylic resins were leveraged from reference device K182789.

The subject device also includes splints additively manufactured from a new light-cured resin photopolymer material. The photopolymer resin is composed of acrylate/methacrylate polymers and is manufactured using cDLM methods. The proposed splints are similar in material composition and utilize similar manufacturing methods as the acrylic/methacrylic resins used to fabricate splints via DLP methods previously evaluated under reference device K182789.

Subject devices undergo similar manufacturing processes and identical post-processing procedures (cleaning & sterilization) as the primary predicate and reference device, K182789.

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Pyrogenicity Testing

LAL endotoxin testing was conducted according to AAMI ANSI ST72 to address the presence of bacterial endotoxins. 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 (K191028). 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 outputs utilizing 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 demonstrate 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 Data – Clinical

Risk mitigation assessments have been completed based on FDA guidance, *"Premarket Assessment of Pediatric Medical Devices,"* issued March 24, 2014, to demonstrate the safety and effectiveness for use of the IPS output devices in the pediatric population. These risk assessments evaluated the following risk factors for pediatric patients: age, size, growth and development, body habitus, developmental milestones, pathophysiology, behavioral factors, psychosocial factors, human factors, surgical factors, and cumulative effects from repeat or unplanned radiation exposure (i.e., CT scan).

The short-term and long-term mitigations for both children and adolescents are similar with regard to implantation. The patient's anatomy and the approving medical practitioner will dictate the size of the implant. Assuming no physes are violated when placing the implant, there are no short-term concerns when placing the patient-specific implant. The most challenging long-term impact for both subpopulations is use of permanent implants in a growing patient. There is a possibility that an implant may restrict growth and development when implanted into a maturing individual. The surgeon performing the procedure will determine whether the implant needs to be removed long-term.

Unplanned or repeat radiation exposure prior to or following the pediatric patient's initial surgery is a risk that is mitigated by device labeling to include special considerations for pediatric populations to minimize ionizing radiation by using low-dose and child-size CT scan protocols when deemed appropriate based on patient size, weight, height, and clinical needs.

To demonstrate clinical performance of KLS Martin IPS implants in the pediatric subpopulations of children (2 years of age to < 12 years of age) and adolescents (12 years of age – 21 years of age), 6 clinical studies including patients 18 months of age through 18 years of age were analyzed following the recommendations of FDA Guidance, *"Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices,* Aug 2017."

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	Patient Age	Patient Subgroup	Treatment	Results & Analysis
Dalena M., et al. (2020)	1 year – 18 years	Infant, child, & adolescent	Standard bone plate fixation	We identified 82 patients aged 18 years or younger who had sustained a panfacial fracture. The mean age at the time of injury was 12.9 years, with a male predominance of 64.9%. A total of 335 fractures were identified on radiologic imaging. The most common etiologies were motor vehicle accidents and pedestrians being struck. Orbital, frontal sinus, nasal, and zygoma fractures were the most common fractures. The most common concomitant injuries were traumatic brain injury, intracranial hemorrhage, and skull fracture. Surgical repair was required in 38 patients. Pediatric panfacial fractures are rare occurrences; however, the impact of these injuries can be devastating, with concomitant life-threatening injuries and complications. Given the lack of literature, as well as the preventable nature of these injuries, we hope this study can address primary prevention strategies and provide insight toward the management and characteristics of these fractures.
Eckardt A., et al. (2010)	18 mos. – 15 years	Infant, child, & adolescent	Standard bone plate fixation, standard resorbable fixation	Although autogenous rib grafts have no relevance in the restoration of mandibular bone defects occurring after ablative tumor surgery due to limited bone stock and the availability of other donor areas, they are a useful surgical alternative following tumor surgery in infants. We here report on a 2, 5, 8, and 15-year follow-up of four children who were diagnosed with benign tumors of the mandible with osseous destruction at the age of 4, 6, 15, and 18 months, respectively. In general, various donor sites (rib graft, free and revascularized iliac crest, revascularized fibula) are available for the restoration of mandibular continuity defects. Our four patients clearly demonstrate that autogenous rib grafts for mandibular restoration in infancy are reliable and a useful surgical alternative. The rib graft was stable with minimal or no signs of resorption even after 15 years.
Gray R., et al. (2017)	44 mos. – 17 years	Children & adolescents	Patient-specific surgical plan with bone plate fixation or distraction device	A retrospective analysis of thirteen patients who underwent 3D, CAD/CAM-assisted preoperative surgical planning between 2012 and 2016 was performed. All CAD/CAM assisted surgical planning was done with a third-party vendor (either 3D Systems or Materialise). Cutting and positioning guides as well as models were produced based on the virtual plan. Surgeries included free fibula mandible reconstruction (n=4), Lefort I osteotomy and distraction (n=2), Lefort II osteotomy with monobloc distraction (n=1), expansion of the posterior vault for correction of chiari malformation (n=3), and secondary orbital and midface reconstruction for facial trauma (n=3). In all cases we found presurgical planning was helpful to improve accuracy and significantly decrease intra-operative time. In cases where distraction was used, the planned and actual vectors were found to be accurate with excellent clinical outcomes.
Precious D., et al. (1985)	6 years – 15 years	Children & adolescents	Standard bone plate fixation	Surgery for the correction of dentofacial deformities can be performed on children and adolescent patients with little morbidity and few complications.
	11 years – 14 years			The correction of dentofacial deformities in children using orthodontic and surgical means can be carried out reliably if careful attention is paid to the systematic evaluation of each deformity. Selected cases from more than 100 children whom we have treated are presented to illustrate salient clinical features of specific deformities.
Schendel S., et al. (1978)	8 years – 16 years	Children & adolescents	Standard bone plate fixation	The surgical orthodontic correction of mandibular deficiency in growing children (8 to 16 years of age) can be employed to achieve excellent results. Mandibular advancement by a modified sagittal osteotomy proves to be an acceptable procedure with good skeletal stability. Dentofacial growth following surgery will be harmonious and not adversely affected. Direction of growth varies, with the mandibular plane angle becoming more vertical with an increasing mandibular plane angle.
Steinbacher D. (2015)	Not specified	Neonate, infant, child, adolescent, & adult	Patient-specific bone plate fixation	Three-dimensional surgical analysis and planning have several advantages. The primary advantage is the ability to comprehensively see and define the problems and understand the preoperative anatomy. It allows for a virtual run through of different scenarios to arrive at the best overall treatment choice. Guides, splints, and plates can be fabricated to help reproduce the digital plan in reality. In conclusion, 3D planning enhances efficiency, accuracy, creativity, and reproducibility in craniomaxillofacial surgery.

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Based on published literature findings of the subject device and similar bone plate devices and the results from the risk analysis, it can be concluded that the subject device can be used for expanded indications for the treatment of children (2 years of age to < 12 years of age) and adolescents (12 years of age – 21 years of age), if additional precautions are taken into account:

*Important considerations in achieving quality outcomes for the treatment of facial deformities in growing patients include accurate diagnosis and patient selection and proper treatment planning***.**

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 non-clinical performance testing, a review of clinical performance data, risk analysis, and the 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 and predicate devices does not raise new or different questions of safety and effectiveness. Therefore, the subject device is substantially equivalent to the predicate device.