KLS-Martin L.P.
Gary Moore
Quality Management and Regulatory Affairs Manager
11201 Saint Johns Industrial Pkwy S
Jacksonville, Florida 32246

September 13, 2018

Re: K181241
Trade/Device Name: KLS Martin Individual Patient Solutions (IPS) Planning System
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZJ, LLZ
Dated: September 7, 2018
Received: September 10, 2018

Dear Gary Moore:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mary S. Runner -S

forTina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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)*

K181241

Device Name

KLS Martin Individual Patient Solutions (IPS) Planning System

Indications for Use *(Describe)*

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.

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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K181241
510(k) Summary
21 CFR 807.92

Submitter:	KLS-Martin L.P. 11201 Saint Johns Industrial Pkwy S Jacksonville, FL 32246
Contact Person:	Gary Moore Quality Management and Regulatory Affairs Manager Phone: 800-625-1557 Email: gmoore@klsmartin.com
Date Prepared:	September 13, 2018
Trade Name:	KLS Martin Individual Patient Solutions (IPS) Planning System
Common Name:	System for the creation of patient specific anatomical models, cutting/marking guides, splints, and case reports
Classification Name:	Bone Cutting Instruments and Accessories (21 CFR 872.4120); System, Image Processing, Radiological (21 CFR 892.2050
Regulatory Class:	II
Product Code:	DZJ, LLZ
Predicate Device:	VSP System **(K120956)** - Primary
Reference Devices:	KLS Martin Individual Patient Solutions **(K163579)** KLS Mini Osteosynthesis System **(K943347)** KLS Martin Centre-Drive Drill-Free Screws **(K971297)**
Device Description:	The KLS Martin Individual Patient Solutions (IPS) Planning System is a collection of software and associated additive manufacturing (rapid prototyping) equipment intended to provide a variety of outputs to support reconstructive and orthognathic surgeries. The system uses electronic medical images of the patients' anatomy (CT data) with input from the physician, to manipulate original patient images for planning and executing surgery. The system processes the medical images and produces a variety of patient specific physical and/or digital output devices which include anatomical models, guides, splints and case reports.
Indications for Use:	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.

Technological Characteristics/Substantial Equivalence Discussion:

The intended use of the subject device, KLS Martin Individual Patient Solutions (IPS) Planning System, is similar to the predicate device, VSP System (K120956):

The subject and primary predicate devices are 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 through the virtual planning software systems 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. These physical outputs can be anatomical models, guides, splints, templates, and case reports. All digital data and physical devices are used to aid the surgeon during maxillofacial surgeries. They are both also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

Similarities to Predicate

Both the subject and primary 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.

Both systems use additive manufacturing methods to produce physical output devices that include patient specific 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.

Materials used in the manufacture of the output devices are similar in that both the subject and predicate devices use biocompatible polymers/acrylic resins. All output devices from both systems are provided non-sterile and must be sterilized by the end user prior to use. Validated sterilization studies were performed to ensure a sterility assurance level (SAL) of 10^{-6}.

Output devices in both systems are temporarily fixated with screws of varying sizes and lengths to aid the surgeon in cutting and marking bone more precisely and accurately. In addition, both devices require trained employees/engineers who utilize the software applications to manipulate data and work with the physician to create the virtual planning session. The physician provides input for model manipulation and interactive feedback through viewing of digital models of system outputs that are modified by the trained employee/engineer during the planning session.

Differences to Predicate

The indications for use statements differ slightly in that the predicate device stipulates physical outputs to include "anatomical models, templates, and surgical guides" whereas the subject device includes "anatomical models, guides, splints, and case reports." The predicate device includes splints and case reports in the narrative description, but splints and case reports were included in the indications for use of the subject device to describe all physical outputs.

The subject device utilizes four (4) commercially off-the-shelf (COTS) software applications for image segmentation and manipulation, whereas the predicate device utilizes thirteen (13) pieces of software that is a combination of COTS and custom.

Materials used in the manufacture of the subject output devices are synthetic polymers, acrylic resins, and titanium (CP titanium & Titanium Alloy). The predicate device manufactures output devices from acrylic and polymers only and uses surgical grade stainless steel cutting and drilling inserts for use in the cutting guides.

In addition, the subject device uses previously cleared fixation screws that are utilized for temporary guide fixation during cutting and marking of the bone. The screws range from 1.5 mm – 2.7 mm with lengths of 4 mm – 22 mm. The predicate device does not indicate screw diameter or length for temporary fixation of cutting guides.

Reference Devices

The KLS Martin Individual Patient Solutions (K163579) has been included as a reference device to address differences in technological characteristics between the KLS Martin IPS Planning System and the predicate device with regard to material composition, biocompatibility, manufacturing process, performance testing, as well as cleaning and sterilization for titanium guides. The KLS Martin IPS Planning System titanium guides are manufactured from identical materials (CP Titanium & Titanium Alloy), undergo the same manufacturing processes, have the same biocompatibility, demonstrate similar performance characteristics, and are cleaned and sterilized using the same validated methods as the titanium implants in the KLS Martin Individual Patients Solutions clearance (K163579).

The KLS Mini Osteosynthesis System (K943347) has been included as a reference device to address the differences in screw dimensions from the reference device KLS Martin Individual Patient Solutions (K163579). In reference device K163579, screw dimensions range from 2.0 mm – 3.2 mm with lengths of 5 mm – 22 mm. The KLS Mini Osteosynthesis System has been included to cover the 1.5 mm screw dimensions and a minimum length down to 4 mm that is identical to the subject device temporary fixation screws.

The KLS Martin Centre-Drive Drill-Free Screw (K971297) has been included as a reference device to address the difference in screw dimension and style from the reference device KLS Martin Individual Patient Solutions (K163579). In reference device K163579, screw dimensions ranged from 2.0 mm – 3.2 mm with lengths of 5 mm – 22 mm and a drill-free screw style. The KLS Martin Centre-Drive Drill-Free Screw has been included to cover the 1.5 mm screw dimensions with a drill-free screw style that is identical to the subject device temporary fixation screws.

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Device Comparison Table					
	KLS Martin IPS Planning System **(Subject Device)**	**Medical Modeling VSP® System** **K120956** **(Primary Predicate)**	**KLS Martin Individual Patient Solutions** **K163579** **(Reference Device)**	**KLS Mini Osteosynthesis System** **K943347** **(Reference Device)**	**KLS Martin Centre-Drive Drill-Free Screw** **K971297** **(Reference Device)**
Indications for Use	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 VSP® 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 VSP® 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, templates, and surgical guides for use in maxillofacial surgery. The VSP® System is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options.	KLS Martin Individual Patient Solutions implant devices are intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.	1) Fractures 2) Osteotomies 3) Reconstruction procedures	KLS Martin Centre-Drive Drill-Free Screws are intended for use in rigid internal fixation of the oral-maxillo-cranio-facial bones. The bone screws are used to anchor plates which are contoured to fit the bony surface and stabilize the bone fragments. The addition of the self drilling feature is the only difference between the submitted device and the predicate device referenced.

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Device Comparison Table					
	KLS Martin IPS Planning System **(Subject Device)**	**Medical Modeling VSP® System** **K120956** **(Primary Predicate)**	**KLS Martin Individual Patient Solutions** **K163579** **(Reference Device)**	**KLS Mini Osteosynthesis System** **K943347** **(Reference Device)**	**KLS Martin Centre-Drive Drill-Free Screw** **K971297** **(Reference Device)**
Contraindications	1. Obvious infections. 2. Hypersensitivity to foreign bodies. 3. Circulatory problems, systemic diseases, and metabolic disorders. 4. Insufficient or inadequate bone tissue. 5. Secondary diseases such as degenerative processes that may negatively influence the healing process. 6. Interventions carried out in a non-sterile environment (e.g. paranasal sinuses). 7. Regions exposed to inappropriate forces or excessive weight loads. 8. Patients unwilling or unable to follow instructions during the postoperative phase due to their mental, neurological, or physical condition. 9. Bone tumors located	The models, templates and guides from the VSP System and the associated case report should not be used if any of the following occur: 1. Patient has an active infection. 2. Significant changes to patient's anatomy have occurred since the medical scan used for product definition was obtained.	1. Obvious infections. 2. Hypersensitivity to foreign bodies. 3. Suspected sensitivity to the implant material. 4. Circulatory problems, systemic diseases and metabolic disorders. 5. Insufficient or inadequate bone tissue. 6. Secondary diseases such as degenerative processes that may negatively influence the healing process. 7. Interventions carried out in a non-sterile environment (e.g. paranasal sinuses). 8. Regions exposed to inappropriate forces or excessive weight loads. 9. Patients unwilling or unable to follow instructions during the postoperative phase due to their mental, neurological or physical condition. 10. Osteoporosis or	1. Active infection. 2. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone or latent infections. 3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions. 4. Foreign body sensitivity. Where material sensitivity is suspected, tests are to be made prior to implantation.	1. Active infection. 2. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone or latent infections. 3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions. 4. Foreign body sensitivity. Where material sensitivity is suspected, tests are to be made prior to implantation.

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	in the implant base region. 10. Obvious drug or alcohol abuse. 11. Significant changes to the patient's anatomy has occurred since the medical scan used for planning purposes was obtained.		osteomalacia or other structural bone damage preventing the stable fixation of implant components. 11. Bone tumors located in the implant base region. 12. Obvious drug or alcohol abuse.		
Classification	21 CFR 872.4120, Class II 21 CFR 892.2050, 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	21 CFR 888.3040, Class II
Product Code	DZJ, LLZ	DZJ, LLC	JEY	JEY	HWC
Material	Anatomical Models: Epoxy/Resin, Acrylic Cutting/Marking Guides: Polyamide, Titanium Alloy (Ti-6Al-4V), CP Titanium Splints: methacrylate	Acrylic and epoxy photopolymers, surgical instrument grade stainless steel	Anatomical Models: Epoxy/Resin, Acrylic Implants: CP Titanium & Titanium Alloy (Ti-6Al-4V)	Implants: CP Titanium & Titanium Alloy (Ti-6Al-4V)	Screws: Titanium Alloy (Ti-6Al-4V)
Manufacturing Method	Epoxy/Resin, Acrylic: Stereolithography (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; Selective Laser Melting) Polyamide: 3D (Additive; Selective Laser Sintering)	3D (Additive)	Epoxy/Resin, Acrylic: Stereolithography (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; Selective Laser Melting)	CP Titanium & Titanium Alloy (Ti-6Al-4V): Traditional (Subtractive)	Titanium Alloy (Ti-6Al-4V): Traditional (Subtractive)

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Sterilization	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)
Temporary/Permanent Screw Diameter	Temporary: 1.5 mm – 2.7 mm	Temporary: Unknown	Permanent: 2.0 mm – 3.2 mm	Permanent: 1.5 mm – 2.0 mm	Permanent: 1.0 mm – 2.0 mm
Temporary/Permanent Screw Length	Temporary: 4 mm – 22 mm	Temporary: Unknown	Permanent: 5 mm – 22 mm	Permanent: 4 mm – 19 mm	Permanent: 2 mm – 9 mm
Temporary/Permanent Screw Style	maxDrive & crossDrive (Drill-Free, locking [ThreadLock Taper Screw - TLTS])	Unknown	maxDrive & crossDrive (Drill-Free, locking [ThreadLock Taper Screw - TLTS])	maxDrive & crossDrive	Centre-Drive & crossDrive (Drill – Free)

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Non-Clinical Performance Data:

Tensile & Bending Testing

Tensile and bending tests were performed on the subject polyamide guides to demonstrate the subject devices made from polyamide can withstand multiple sterilization cycles without degradation and can maintain 85% of its initial tensile strength. This testing also provides evidence of shelf life for the subject polyamide guides in that the material will not degrade or the performance of the device will not be affected within the shelf life period. Shelf life period of the device is 6 months.

Tensile and bending tests for titanium were performed as outlined in the reference device, KLS Martin Individual Patient Solutions (K163579). Results of the testing demonstrate additively manufactured titanium devices are equivalent or better than titanium devices manufactured using traditional (subtractive) methods. The subject titanium devices are identical in formulation, manufacturing processes, and post-processing procedures (cleaning & sterilization) as the reference device, K163579.

Biocompatibility Testing

Biocompatibility endpoints were evaluated in accordance with ISO 10993-1. The battery of cytotoxicity, sensitization, irritation, and chemical/material characterization testing conducted on the subject devices manufactured from polyamide are within the pre-defined acceptance criteria. The above biocompatibility tests were also conducted for titanium and are within the pre-defined acceptance criteria, as outlined in the reference device KLS Martin Individual Patient Solutions (K163579). The results of the testing adequately address biocompatibility for the output devices and their intended use.

Sterilization Testing

Steam sterilization validations were performed for each output device for 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 titanium were leveraged from the reference device, KLS Martin Individual Patient Solutions (K163579). Subject titanium devices are identical in formulation, manufacturing processes, and post-processing procedures (cleaning & sterilization) as the reference device, K163579.

Pyrogenicity Testing

LAL endotoxin testing was conducted according to AAMI ANSI ST72 on the subject devices to address the presence of bacterial endotoxins and ensure they meet pyrogen limit specifications. The results of the testing demonstrate that the KLS Martin IPS Planning System 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 reference device, KLS Martin Individual Patient Solutions (K163579). Subject titanium devices are identical in formulation, manufacturing processes, and post-processing procedures (cleaning & sterilization) as the reference device, K163579.

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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.

Clinical Performance Data:

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

Conclusion:

The KLS Martin IPS Planning System has the same intended use and similar technological characteristics as the predicate and reference devices. Technological differences have been assessed with performance testing presented in this submission. Testing has demonstrated that any differences in technological characteristics do not identify new issues of safety or effectiveness, and concludes the subject device is substantially equivalent to the predicate device.