July 26, 2019

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

Re: K182889
Trade/Device Name: KLS Martin Individual Patient Solutions (IPS) Planning System
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered Simple Cranial Drills, Burrs, Trephines, And Their Accessories
Regulatory Class: Class II
Product Code: PPT
Dated: July 17, 2019
Received: July 18, 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 Matthew Krueger
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine 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)*
K182889

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 computerized tomography (CT) medical scan. 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 and case reports for use in the marking of cranial bone in cranial 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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Section 5
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@klsmartin.com
Date Prepared:	July 25, 2019
Trade Name:	KLS Martin Individual Patient Solutions (IPS) Planning System
Common Name:	System for the creation of patient specific anatomical models, marking guides, and case reports
Classification Name:	Powered Simple Cranial Drills, Burrs, Trephines, and Their Accessories
Regulatory Class:	II, 21 CFR 882.4310
Product Code:	PPT
Predicate Devices:	KLS Martin Individual Patient Solutions (IPS) Planning System **(K181241)** – Primary
Reference Devices:	KLS Martin Individual Patient Solutions **(K163579)** KLS Martin Individual Patient Solutions **(K180962)**
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 cranial 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, and case reports for use in the marking of cranial bone in cranial surgery.
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 computerized tomography (CT) medical scan. 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, and case reports for use in the

marking of cranial bone in cranial 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, KLS Martin Individual Patient Solutions (IPS) Planning System (K181241):

The subject and predicate device are intended for use as a software system and image segmentation system for the transfer of imaging from a computerized tomography (CT) medical scan. 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, and case reports. All digital data and physical devices are used to aid the surgeon during surgery. They are both also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

The indications for use statement for the subject device is nearly identical to the predicate device, differing only in anatomical region and output devices. The anatomical region for which the predicate device is intended is listed as maxillofacial, indicating that the device may be used only for maxillofacial applications. The subject device system is specific to only the cranial region and excludes maxillofacial applications. The change in anatomical region presented in the indications for use statement of the subject device system as compared to the predicate device does not change the therapeutic effects of the device. In addition, the subject device offers output devices that include anatomical models, marking guides, and case reports only. The predicate device offers output devices that include anatomical models, cutting guides, marking guides, splints, and case reports. Splints are not applicable to cranial reconstructive surgeries as they are only intended for orthognathic surgeries.

Similarities to Predicate

Both the subject and primary predicate devices use image data obtained from a CT scan. They both use identical 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. 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.

Design validation activities performed to verify the final finished output device matches the initial input data (.STL) are identical to the predicate and reference devices, K181241 and K163579.

The subject and predicate device specifications are identical in device thickness, width, length, degree of curvature (in-plane and out-of-plane), screw hole spacing and number of screw holes. A comparison of the subject and predicate device specifications is provided in the table below. The marking guides are non-load bearing, non-implantable, and are only temporarily fixated for the duration of the surgery. A thickness range up to 5.0 mm for the

cranial marking guides is to ensure the marking wall is thick enough and clearly visible for accurate marking of bone for resection.

Both systems use traditional (subtractive) and additive manufacturing methods to produce physical output devices that include patient specific anatomical models and guides. In addition, the systems produce digital models and case reports for the physician to use for planning the surgeries or to use during surgery.

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

Both the subject and predicate devices are temporarily fixated with previously cleared screws of varying sizes and lengths to aid the surgeon in marking of bone more precisely and accurately.

Differences to Predicate

The intended use of the subject device system is very similar to the predicate device, differing only in the anatomical region in which the device is intended for. The subject device is intended for cranial regions in cranial surgeries, while the predicate device is intended for maxillomandibular regions for maxillofacial surgeries.

The subject device utilizes the same commercially off-the-shelf (COTS) software applications for image segmentation and manipulation as the predicate device, except for the use of the software application IPS CaseDesigner and MathWorks® MATLAB, which are used to manipulate data for production of splints. The subject device system will not be outputting splints as these are intended for orthognathic surgeries.

The subject devices are temporarily fixated with previously cleared screws that range in diameter sizes of 1.0 mm – 2.7 mm with lengths ranging 2 mm – 22 mm. The predicate devices are temporarily fixated with the same previously cleared screws except for the 1.0 mm and 1.2 mm diameter screws.

The potential impact on substantial equivalence of each technological difference was addressed through risk analysis and verification and validation testing.

Reference Devices

The KLS Martin Individual Patient Solutions (K163579 and K180962) have been included as reference devices to leverage performance testing regarding the material composition (material recycling process, degradation, tensile & bending), biocompatibility, manufacturing processes, as well as cleaning and sterilization for titanium output devices. The KLS Martin IPS Planning System titanium output devices are manufactured from identical materials, undergo the same manufacturing processes (traditional & additive), have the same biocompatibility, demonstrate similar performance characteristics, and are designed, verified, cleaned and sterilized using the same validated methods as the reference devices cleared in K163579 and K180962.

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Device Comparison Table				
	KLS Martin IPS Planning System **(Subject Device)**	**KLS Martin IPS Planning System** **K181241** **(Primary Predicate)**	**KLS Martin Individual Patient Solutions** **K163579** **(Reference Device)**	**KLS Martin Individual Patient Solutions** **K180962** **(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 computerized tomography (CT) medical scan. 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, and case reports for use in the marking of cranial bone in cranial surgery. The IPS Planning System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.	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.	KLS Martin Individual Patient Solutions implant devices are intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.	KLS Martin Individual Patient Solutions implant devices are intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.

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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 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.	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 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.	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 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.	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 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.

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Classification	21 CFR 882.4310, 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	PPT	DZJ, LLZ	JEY	JEY
Material	Anatomical Models: Epoxy/Resin, Acrylic Marking Guides: Polyamide, Titanium Alloy (Ti-6Al-4V), CP Titanium	Anatomical Models: Epoxy/Resin, Acrylic Cutting/Marking Guides: Polyamide, Titanium Alloy (Ti-6Al-4V), CP Titanium Splints: methacrylate	Anatomical Models: Epoxy/Resin, Acrylic Implants: CP Titanium & Titanium Alloy (Ti-6Al-4V)	Anatomical Models: Epoxy/Resin, Acrylic Cutting Guides: CP Titanium & Titanium Alloy (Ti-6Al-4V) Implants: CP Titanium & 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)	Epoxy/Resin, Acrylic: Stereolithography (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; Selective Laser Melting) Polyamide: 3D (Additive; Selective Laser Sintering)	Epoxy/Resin, Acrylic: Stereolithography (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; Selective Laser Melting)	Epoxy/Resin, Acrylic: Stereolithography (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; Selective Laser Melting)
Software	Materialise Mimics (K073468) Geomagic® Freeform Plus™	Materialise Mimics (K073468) Geomagic® Freeform Plus™ IPS CaseDesigner (K161634) MathWorks® MATLAB	Materialise Mimics (K073468) Geomagic® Freeform Plus™	Materialise Mimics (K073468) Geomagic® Freeform Plus™
Sterilization	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)

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Target Population	Adults	Adolescents & Adults	Not applicable	Not applicable
Anatomical Sites	Cranial Areas	Maxillary & Mandibular Areas	Mandibular Areas	Mandibular Areas
Guide Specifications				
Thickness	Marking Guide Min: 1.0 mm Max: 5.0 mm	Cutting/Marking Guide Min: 1.0 mm Max: 5.0 mm	Not applicable	Cutting/Marking Guide Min: 1.0 mm Max: 3.0 mm
Width	Marking Guide Min: 7 mm Max: 200 mm	Cutting/Marking Guide Min: 7 mm Max: 200 mm	Not applicable	Cutting/Marking Guide Min: 7 mm Max: 200 mm
Length	Marking Guide Min: 15 mm Max: 350 mm	Cutting/Marking Guide Min: 15 mm Max: 350 mm	Not applicable	Cutting/Marking Guide Min: 31 mm Max: 320 mm
Degree of curvature (in-plane)	Marking Guide Min: 90° Max: 180°	Cutting/Marking Guide Min: 90° Max: 180°	Not applicable	Cutting/Marking Guide Min: 90° Max: 180°
Degree of curvature (out-of-plane)	Marking Guide Min: 60° Max: 180°	Cutting/Marking Guide Min: 60° Max: 180°	Not applicable	Cutting/Marking Guide Min: 60° Max: 180°
Screw Hole spacing	Marking Guide Min: ≥4.5 mm Max: No Max	Cutting/Marking Guide Min: ≥4.5 mm Max: No Max	Not applicable	Cutting/Marking Guide Min: ≥8 mm Max: No Max

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No. of Holes	Marking Guide Min: 2 Max: Depends on length and hole spacing	Cutting/Marking Guide Min: 2 Max: Depends on length and hole spacing	Not applicable	Cutting/Marking Guide Min: 2 Max: Depends on length and hole spacing
Screw Specifications				
Temporary/Permanent Screw Diameter	Temporary: 1.0 mm – 2.7 mm	Temporary: 1.5 mm – 2.7 mm	Permanent: 2.0 mm – 3.2 mm	Permanent & Temporary: 2.0 mm – 3.2 mm
Temporary/Permanent Screw Length	Temporary: 2 mm – 11 mm	Temporary: 4 mm – 22 mm	Permanent: 5 mm – 22 mm	Permanent & Temporary: 5 mm – 22 mm
Temporary/Permanent Screw Style	maxDrive & crossDrive (Drill-Free, locking [ThreadLock Taper Screw -TLTS])	maxDrive & crossDrive (Drill-Free, locking [ThreadLock Taper Screw -TLTS])	maxDrive & crossDrive (Drill-Free, locking [ThreadLock Taper Screw -TLTS])	maxDrive & crossDrive (Drill-Free, locking [ThreadLock Taper Screw -TLTS])

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 devices manufactured from polyamide are within the pre-defined acceptance criteria, as outlined in the predicate device KLS Martin Individual Patient Solutions (IPS) Planning System (K181241). 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). In addition, acute systemic toxicity, material-mediated pyrogenicity, and indirect (extract) hemolysis testing were also performed on devices manufactured from polyamide and titanium and are within the pre-defined acceptance criteria. The results of all 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 devices manufactured from polyamide (guides) and epoxies/resins/acrylics (anatomical models) were leveraged from predicate device, KLS Martin Individual Patient Solutions (IPS) Planning System (K181241). Validations for devices manufactured from titanium (guides) were leveraged from the reference devices, KLS Martin Individual Patient Solutions (K163579 & K180962). Subject devices manufactured from polyamide and epoxies/resins/acrylics are identical in formulation, manufacturing processes, biocompatibility, and post-processing procedures (cleaning & sterilization) as the predicate device, K181241. Subject devices manufactured from titanium are identical in formulation, manufacturing processes, biocompatibility, and post-processing procedures (cleaning & sterilization) as the reference devices, K163579 and K180962.

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 that have contact with cerebrospinal fluid (< 2.15 EU/device) and meet pyrogen limit specifications. LAL endotoxin testing for titanium was leveraged from the reference device, KLS Martin Individual Patient Solutions (K163579). Subject polyamide and epoxy/resin/acrylic devices are identical in formulation, manufacturing processes, biocompatibility, and post-processing procedures (cleaning & sterilization) as the predicate device, K181241. Subject titanium devices are identical in formulation, manufacturing processes, biocompatibility, and post-processing procedures (cleaning & sterilization) as the reference device, K163579.

Software Verification and Validation

Software verifications and validations were 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 which was 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 very similar technological characteristics as the predicate device and reference devices. Technological differences have been assessed with non-clinical performance testing presented in this submission. Testing has demonstrated that any differences in technological characteristics do not raise new issues of safety or effectiveness and concludes the subject device is substantially equivalent to the predicate device.