March 11, 2020

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

Re: K192979
Trade/Device Name: KLS Martin Individual Patient Solutions (IPS) Planning System
Regulation Number: 21 CFR 888.3030
Regulation Name: Orthopaedic Surgical Planning and Instrument Guides
Regulatory Class: Class II
Product Code: PBF, LLZ
Dated: December 6, 2019
Received: December 12, 2019

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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K192979

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 in an additive manufacturing portion of the system that produces physical outputs including anatomical models, guides, and case reports for use in thoracic (excluding spine) and reconstructive surgeries. 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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K192979
510(k) Summary
21 CFR 807.92

Submitter:	KLS-Martin L.P. 11201 Saint Johns Industrial Pkwy S. Jacksonville, FL 32246
Contact Person:	Pam Martin, RAC, MSc Regulatory Affairs Project Manager Phone: 800-625-1557 Email: pmartin@klsmartinusa.com
Date Prepared:	December 6, 2019
Trade Name:	KLS Martin Individual Patient Solutions (IPS) Planning System
Common Name:	System for the creation of patient specific anatomical models, cutting/marking guides, and case reports
Classification Name:	Orthopaedic Surgical Planning and Instrument Guides; System, Image Processing, Radiological
Regulatory Class:	II
Product Codes:	PBF, LLZ
Regulation Number:	21 CFR 888.3030, 21 CFR 892.2050
Primary Predicate:	KLS Martin IPS Planning System **(K182789)**
Reference Devices:	KLS Martin IPS Planning System **(K181241)** KLS Martin Individual Patient Solutions **(K163579)** KLS Martin Thoracic Plating System **(K153482)**

Device Description

The KLS Martin Individual Patient Solutions (IPS) Planning System is a collection of software and associated additive manufacturing equipment intended to provide a variety of outputs to support thoracic (excluding spine) and reconstructive 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.

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 in an additive manufacturing portion of the system that produces physical outputs including anatomical models, guides, and case reports for use in thoracic (excluding spine) and reconstructive surgeries. The IPS Planning System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

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Technological Characteristics/Substantial Equivalence Discussion:

The intended use of the subject device, KLS Martin Individual Patient Solutions (IPS) Planning System, is identical to the primary predicate device, the KLS Martin Individual (IPS) Patient Solutions System (K182789):

The subject and primary predicate devices are intended for use 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 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 reconstructive surgeries. They are both also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

The indications for use statement of the subject device differs in anatomical location and system outputs from the primary predicate, K182789. K182789 is cleared for use in maxillofacial surgery. The subject device is indicated for thoracic (excluding spine) surgery.

The potential impact on substantial equivalence for each technological difference has been addressed through risk analysis as well as verification and validation testing.

Similarities to Predicate

The subject and primary predicate devices share the same fundamental principle of operation – a system that processes original patient medical images (i.e., CT scan) and produces a variety of patient-specific physical and/or digital output devices for planning and executing surgery.

The subject device shares identical technological characteristics as the primary predicate regarding software, material composition, biocompatibility, manufacturing process, performance testing, as well as cleaning and sterilization.

Both the subject and primary predicate devices use image data obtained from medical scanners, such as a CT scan. The subject device utilizes two (2) commercially off-the-shelf (COTS) software applications for image segmentation and manipulation identical to what was evaluated in the primary predicate device, K182789. The validated commercially off-the-shelf (COTS) software applications are used 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.

Both systems use 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 surgeries or to use during surgery.

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, K182789.

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All output devices from both systems are provided non-sterile and must be sterilized by the end user prior to use. Steam sterilization validation studies were performed to ensure a sterility assurance level (SAL) of 10^{-6}.

Differences from Predicate

The subject device's indications for use differs from the primary predicate in anatomical region. The skeletal region for which the primary predicate device was cleared includes the mandibular and maxillofacial areas. The subject device will be used in the thoracic region (excluding spine).

Previously cleared specifications for the primary predicate were expanded for the subject device guides based on differences in anatomical region. The maximum thickness of the subject device guides is 20 mm to allow for thickening of areas that guide drilling or cutting paths in the thoracic region. The primary predicate devices in the maxillofacial region pose a greater challenge in terms of limited surgical access, whereas the anatomy of the thoracic region is relatively unobstructed. The increase in thickness for the subject device guides was analyzed for additional risk compared to the primary predicate. The results of the dimensional analysis for the subject device compared to the primary predicate device did not indicate new or different questions of risk or safety and effectiveness. Simulated use of guides intended for use in the thoracic region was validated by means of virtual planning sessions with the end-user.

The primary predicate device utilizes four (4) pieces of software that is a combination of COTS and custom to fabricate physical outputs specific to maxillofacial surgeries, including orthognathic splints). The subject device only requires two of the four software applications used by the predicate in order to produce anatomical models, guides, and case reports. Splints are for orthognathic use only and not applicable to this submission.

The primary predicate patient population includes all pediatric subpopulations (neonate, infant, child, adolescent) and adults, whereas the subject device limits the pediatric subpopulations to child and adolescent, but still includes the adult population.

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 for use in the pediatric subpopulations.

Reference Devices

KLS Martin Individual Patient Solutions (K163579) and the KLS Martin IPS Planning System (K181241) have been included as reference devices to leverage performance testing regarding the material composition (material recycling process, degradation, tensile & bending). Subject devices are manufactured from identical materials, undergo the same manufacturing processes, 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 K181241.

The KLS Martin Thoracic Plating System, K153482, has been included as a reference device to address differences in technological characteristics between the subject and primary predicate devices.

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- Anatomy: The primary predicate device was cleared for use in the maxillofacial skeleton, including mandible, whereas the subject device is indicated for the thoracic region (excluding spine), which is identical to the reference device.
- Fixation screws: The primary predicate screws range from 1.5 mm – 2.7 mm in diameter with lengths of 4 mm – 22 mm, whereas the subject device screws range from 2.3 mm – 3.2mm in diameter with lengths from 7 mm – 17 mm, which is identical to what was cleared in the reference device.

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	KLS Martin IPS Planning System (Subject Device)	KLS Martin IPS Planning System K182789 (Primary Predicate)	KLS Martin IPS Planning System K181241 (Reference Device)	KLS Martin Individual Patient Solutions K163579 (Reference Device)	KLS Martin Thoracic Plating System K153482 (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 in an additive manufacturing portion of the system that produces physical outputs including anatomical models, guides, and case reports for use in thoracic (excluding spine) and reconstructive surgeries. 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.	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.	The KLS Martin Thoracic Fixation System is indicated for use in the stabilization and fixation of fractures in the chest wall including sternal reconstructive surgical procedures, trauma, or planned osteotomies.

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	KLS Martin IPS Planning System (Subject Device)	KLS Martin IPS Planning System K182789 (Primary Predicate)	KLS Martin IPS Planning System K181241 (Reference Device)	KLS Martin Individual Patient Solutions K163579 (Reference Device)	KLS Martin Thoracic Plating System K153482 (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. 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. 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. Active Infection. 2. Not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical or lumbar spine. 3. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone or latent infections. 4. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions. 5. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation.

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	KLS Martin IPS Planning System (Subject Device)	KLS Martin IPS Planning System K182789 (Primary Predicate)	KLS Martin IPS Planning System K181241 (Reference Device)	KLS Martin Individual Patient Solutions K163579 (Reference Device)	KLS Martin Thoracic Plating System K153482 (Reference Device)
Classification	21 CFR 892.2050, Class II 21 CFR 888.3030, Class II	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 888.3030, Class II
Product Code	LLZ, PBF	DZJ, LLZ	DZJ, LLZ	JEY	HRS
Material	Anatomical Models: Epoxy/Resin, Acrylic Cutting/Marking Guides: PA, Ti-6Al-4V, CP Titanium	Anatomical Models: Epoxy/Resin, Acrylic Cutting/Marking Guides: PA, Ti-6Al-4V, CP Titanium Splints: methacrylate	Anatomical Models: Epoxy/Resin, Acrylic Cutting/Marking Guides: PA, Ti-6Al-4V, CP Titanium Splints: methacrylate	Not applicable	CP Titanium or Titanium Alloy (Ti-6Al-4V)
Manufacturing Method	Epoxy/Resin, Acrylic: 3D (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; SLM) Polyamide: 3D (Additive; SLS)	Epoxy/Resin, Acrylic: 3D (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; SLM) Polyamide: 3D (Additive; SLS)	Epoxy/Resin, Acrylic: 3D (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; SLM) Polyamide: 3D (Additive; SLS)	Anatomical Models: Epoxy/Resin, Acrylic Implants: CP Titanium & Titanium Alloy (Ti-6Al-4V)	CP Titanium: Traditional (Subtractive) Ti-6Al-4V: Traditional (Subtractive)
Software	Materialise Mimics (K073468) Geomagic® Freeform Plus™	Materialise Mimics (K073468) Geomagic® Freeform Plus™ IPS CaseDesigner (K161634) MathWorks® MATLAB	Materialise Mimics (K073468) Geomagic® Freeform Plus™ IPS CaseDesigner (K161634) MathWorks® MATLAB	Materialise Mimics (K073468) Geomagic® Freeform Plus™	Not applicable
Target Population	Child, Adolescent, & Adult	Pediatric & Adult	Adolescent & Adult	Not applicable	Not applicable
Sterilization	Non-sterile (steam)	Non-sterile (steam)	Non-sterile (steam)	Non-sterile (steam)	Sterile (Gamma) or Non-sterile (steam)
Anatomical Sites	Thoracic	Mandibular and Maxillofacial	Mandibular and Maxillofacial	Mandibular	Thoracic

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	KLS Martin IPS Planning System (Subject Device)	KLS Martin IPS Planning System K182789 (Primary Predicate)	KLS Martin IPS Planning System K181241 (Reference Device)	KLS Martin Individual Patient Solutions K163579 (Reference Device)	KLS Martin Thoracic Plating System K153482 (Reference Device)
Guide Specifications					
Thickness	Cutting/Marking Guide Min: 1.0 mm Max: 20 mm	Cutting/Marking Guide Min: 1.0 mm Max: 5.0 mm	Cutting/Marking Guide Min: 1.0 mm Max: 5.0 mm	Not applicable	Not applicable
Width	Cutting/Marking Guide Min: 7 mm Max: 300 mm	Cutting/Marking Guide Min: 7 mm Max: 200 mm	Cutting/Marking Guide Min: 7 mm Max: 200 mm	Not applicable	Not applicable
Length	Cutting/Marking Guide Min: 7 mm Max: 300 mm	Cutting/Marking Guide Min: 15 mm Max: 350 mm	Cutting/Marking Guide Min: 15 mm Max: 350 mm	Not applicable	Not applicable
Degree of curvature (in-plane)	Cutting/Marking Guide Min: N/A Max: N/A	Cutting/Marking Guide Min: 90° Max: 180°	Cutting/Marking Guide Min: 90° Max: 180°	Not applicable	Not applicable
Degree of curvature (out-of-plane)	Cutting/Marking Guide Min: N/A Max: N/A	Cutting/Marking Guide Min: 60° Max: 180°	Cutting/Marking Guide Min: 60° Max: 180°	Not applicable	Not applicable
Screw hole spacing	Cutting/Marking Guide Min: ≥4.5 mm Max: No Max	Cutting/Marking Guide Min: ≥4.5 mm Max: No Max	Cutting/Marking Guide Min: ≥4.5 mm Max: No Max	Not applicable	Not applicable
No. of holes	Cutting/Marking Guide Min: N/A Max: N/A	Cutting/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	Not applicable
Screw Specifications					
Diameter	Temporary: 2.3 mm - 3.2 mm	Temporary : 1.5 mm - 2.7 mm	Temporary: 1.5 mm – 2.7 mm	Permanent: 2.0 mm – 3.2 mm	Permanent: 2.3 mm - 3.2 mm
Length	Temporary: 7 mm - 17 mm	Temporary: 4 mm – 22 mm	Temporary: 4 mm – 22 mm	Permanent: 5 mm – 22 mm	Permanent: 7 mm - 17 mm
Style	maxDrive (Drill-Free, non-locking, locking)	maxDrive & crossDrive (Drill-Free, non-locking, locking, TLTS)	maxDrive & crossDrive (Drill-Free, locking, TLTS)	maxDrive & crossDrive (Drill-Free, locking, TLTS)	maxDrive (Drill-Free, locking)

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Non-Clinical Performance Data:

Performance Testing

Tensile and bending tests were performed to demonstrate that the subject devices made from polyamide can withstand multiple sterilization cycles without degradation and can maintain 85% of its initial tensile strength as outlined in the reference device, KLS Martin Individual Patient Solutions (IPS) Planning System (K181241). 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.

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 substantially equivalent to 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 were within the pre-defined acceptance criteria, and therefore, adequately addresses 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.

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.

Software Verification and Validation

Software verification and validation was performed on each individual software application used in the planning and design of the output devices derived from 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.

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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 primary predicate device. Technological differences have been addressed by leveraging performance data from the primary predicate and reference devices in addition to validating simulated use (planning session). No new or different questions of safety or effectiveness were identified, which supports the conclusion that the subject device system is substantially equivalent to the predicate device.