August 31, 2020

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

Re: K201052
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 30, 2020
Received: July 31, 2020

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,

Xiaolin Zheng, Ph.D.
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)*
K201052

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 and cutting 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. Information provided by the software and device output is not intended to eliminate, replace, or substitute, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.

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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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 Regulatory Affairs Project Manager Phone: 800-625-1557 Email: katie.rutland@klsmartin.com
Alternate Contact:	Melissa Bachorski RA/QMS Manager Phone: 800-625-1557 Email: RA_QA@klsmartin.com
Date Prepared:	August 31, 2020
510(k) Number:	K201052
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:	Cranial Surgical Planning and Instrument Guides (21 CFR 882.4310)
Regulatory Class:	II
Product Code:	PPT
Predicate Device:	KLS Martin Individual Patient Solutions (IPS) Planning System **(K182889)**
Reference Devices:	KLS Martin Individual Patient Solutions (IPS) Planning System **(K182789)** Stryker PEEK Customized Cranial Implant **(K190229)**

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 and cutting 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 and cutting 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.

Information provided by the software and device output is not intended to eliminate, replace, or substitute, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.

Technological Characteristics/Substantial Equivalence Discussion:

The intended use of the subject device, KLS Martin Individual Patient Solutions (IPS) Planning System, is identical to the predicate device, the KLS Martin Individual (IPS) Patient Solutions System (K188789):

The subject and 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 cranial 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 is nearly identical to the predicate, K182889, differing in system outputs. The predicate, K182889, is cleared for use in the marking of bone in cranial surgery. The subject device is indicated for the marking and cutting of cranial bone in cranial surgery. The potential impact on substantial equivalence with regard to each technological difference has been addressed through risk analysis as well as verification and validation testing.

Similarities to Predicate

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

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

Both the subject and predicate devices use image data obtained from CT scans. 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 predicate device, K182889. 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.

Design validation activities to verify the final finished output device matches the initial input data (.STL) are identical to the predicate and reference devices, K182889 and K182789.

Materials used in the manufacture of the subject output devices are polyamide, acrylic resins, and titanium (CP titanium & Titanium Alloy) identical to what was evaluated in the predicate device, K182889.

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}.

Differences from Predicate

The subject device's indications for use is nearly identical to the predicate device, differing in system outputs. The predicate, K182889, is cleared for use in the marking of bone in cranial surgery. The subject device is indicated for the marking and cutting of cranial bone in cranial surgery.

The IPS Planning System includes cutting and positioning guides, whereas the predicate only includes marking guides. Cutting and positioning guides were included as part of this device system to aid in cranial pediatric surgeries (e.g., craniosynostosis, congenital cranial deformities, etc.).

The predicate patient population includes adults only, whereas the subject device includes pediatric (neonate, infant, children, adolescents) and adult patient populations.

Risk assessments have been performed based on FDA guidance, "*Premarket Assessment of Pediatric Medical Devices*, March 24, 2014" for these subpopulations with supporting peer-reviewed clinical studies to demonstrate the safety and effectiveness of the subject device for use in the pediatric subpopulations.

Reference Devices

The KLS Martin Individual Patient Specific Planning System, K182789, and the Stryker PEEK Customized Cranial Implant Kit, K190229 have been included as reference devices to address differences in technological characteristics between the subject and predicate devices.

- Target Population: The predicate device was cleared for use in the adult patient population only, whereas the subject device includes pediatric (neonate, infant, children, adolescents) and adult patient populations, which is similar to the reference devices. K182789 includes all pediatric subpopulations and adults, while K190229 includes patients 3.5 years of age and older. Risk mitigation studies for pediatric patients were completed in both reference devices along with verbiage provided in the labelling to mitigate any risks (i.e., radiation exposure).

Device Comparison Table				
	KLS Martin IPS Planning System (Subject Device)	**KLS Martin IPS Planning System K182889 (Primary Predicate)**	**KLS Martin IPS Planning System K182789 (Reference)**	**Stryker PEEK Customized Cranial Implant Kit K190229 (Reference)**
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 and cutting 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. Information provided by the software and device output is not intended to eliminate, replace, or substitute, in whole or in part, the healthcare provider's judgment and analysis of the patient's condition.	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.	The PEEK Customized Cranial Implant Kit is indicated for the augmentation and/or restoration of bony and/or soft tissue deformities in the cranial and craniofacial skeleton (orbital rim, zygoma, and adjacent bone); including but not limited to, the correction and prevention of persistent temporal hollowing (PTH) in patients 3.5 years of age and older.

Device Comparison Table				
	KLS Martin IPS Planning System (Subject Device)	**KLS Martin IPS Planning System K182889 (Primary Predicate)**	**KLS Martin IPS Planning System K182789 (Reference)**	**Stryker PEEK Customized Cranial Implant Kit K190229 (Reference)**
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. 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.	Unknown

Device Comparison Table				
	KLS Martin IPS Planning System (Subject Device)	**KLS Martin IPS Planning System K182889 (Primary Predicate)**	**KLS Martin IPS Planning System K182789 (Reference)**	**Stryker PEEK Customized Cranial Implant Kit K190229 (Reference)**
Classification	21 CFR 882.4310, Class II	21 CFR 882.4310, Class II	21 CFR 872.4120, Class II 21 CFR 892.2050, Class II	21 CFR 882.5320, Class II
Product Code	PPT	PPT	DZJ, LLZ	GWO
Material	Anatomical Models: Epoxy/Resin, Acrylic Cutting/Marking Guides: Polyamide, Ti-6Al-4V, CP Titanium	Anatomical Models: Epoxy/Resin, Acrylic Cutting/Marking Guides: Polyamide, Ti-6Al-4V, CP Titanium	Anatomical Models: Epoxy/Resin, Acrylic Cutting/Marking Guides: PA, Ti 6Al-4V, CP Titanium Splints: methacrylate	Polyether ether ketone (PEEK)
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)	Unknown
Software	Materialise Mimics (K073468) Geomagic® Freeform Plus™	Materialise Mimics (K073468) Geomagic® Freeform Plus™	Materialise Mimics (K073468) Geomagic® Freeform Plus™ IPS CaseDesigner (K161634) MathWorks® MATLAB	Unknown
Target Population	Pediatric & Adult	Pediatric & Adult	Pediatric & Adult	Pediatric & Adult
Sterilization	Non-sterile (steam)	Non-sterile (steam)	Non-sterile (steam)	Non-sterile (steam)
Anatomical Sites	Cranial	Cranial	Mandibular and Maxillofacial	Cranial
Thickness	Cutting/Marking Guide Min: 1.0 mm Max: 5 mm	Cutting/Marking Guide Min: 1.0 mm Max: 5 mm	Cutting/Marking Guide Min: 1.0 mm Max: 5.0 mm	Not applicable

Device Comparison Table				
	KLS Martin IPS Planning System (Subject Device)	**KLS Martin IPS Planning System K182889 (Primary Predicate)**	**KLS Martin IPS Planning System K182789 (Reference)**	**Stryker PEEK Customized Cranial Implant Kit K190229 (Reference)**
Width	Cutting/Marking Guide Min: 7 mm Max: 200 mm	Cutting/Marking Guide Min: 7 mm Max: 200 mm	Cutting/Marking Guide Min: 7 mm Max: 200 mm	Not applicable
Length	Cutting/Marking Guide Min: 15 mm Max: 350 mm	Cutting/Marking Guide Min: 15 mm Max: 350 mm	Cutting/Marking Guide Min: 15 mm Max: 350 mm	Not applicable
Degree of curvature (in-plane)	Cutting/Marking Guide Min: 90° Max: 180°	Cutting/Marking Guide Min: 90° Max: 180°	Cutting/Marking Guide Min: 90° Max: 180°	Not applicable
Degree of curvature (out-of-plane)	Cutting/Marking Guide Min: 60° Max: 180°	Cutting/Marking Guide Min: 60° Max: 180°	Cutting/Marking Guide Min: 60° Max: 180°	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
No. of holes	Cutting/Marking Guide Min: 2 Max: Depends on length and hole spacing	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
Screw Diameter	Temporary: 1.0 mm – 2.7 mm	Temporary: 1.0 mm – 2.7 mm	Temporary: 1.5 mm - 2.7 mm	Not applicable
Screw Length	Temporary: 2 mm – 11 mm	Temporary: 2 mm – 11 mm	Temporary: 4 mm – 22 mm	Not applicable
Screw Style	maxDrive & crossDrive (Drill-Free, non-locking)	maxDrive & crossDrive (Drill-Free, locking [ThreadLock Taper Screw -TLTS])	maxDrive & crossDrive (Drill-Free, non-locking, locking, TLTS	Not applicable

Non-Clinical Performance Data

Tensile & Bending Testing

Tensile and bending tests 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. This testing is identical to the predicate device and is leveraged from K182889.

Tensile and bending tests for titanium were performed as outlined in the predicate device, K182889. 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 predicate device and is leveraged from K182889.

Biocompatibility Testing

Biocompatibility endpoints were evaluated in accordance with ISO 10993-1. The battery of cytotoxicity, sensitization, irritation, chemical/material characterization, acute systemic, material-mediated pyrogenicity, and indirect (extract) hemolysis 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. Biocompatibility testing is identical to the predicate device and is leveraged from K182889.

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. Sterilization testing is identical to the predicate device and is leveraged from K182889.

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. Pyrogenicity testing is identical to the predicate device and is leveraged from K182889.

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. Software verification and validation is identical to the predicate device and is leveraged from K182889.

Simulated Design Validation Testing

Simulated design validation testing was performed using a representative cranial case that was extrapolated to six (6) distinct age ranges for input data (CT scan) equals output data validation. Testing demonstrated that the subject devices passed all acceptance criteria regardless of age or size. Furthermore, it confirms the subject devices to be manufacturable at a high and acceptable level of fidelity, independent of feature size, age of patient, and device size.

Human Factors and Usability Testing

Simulated human factors and usability testing was performed using clinical expert review to analyze the device output across all age ranges for potential use problems and to make recommendations. These output devices (guides, models, and case reports) for each age range (6 total) were sent to three separate clinical experts. In total, eighteen (18) cases were analyzed and the results showed that no potential risks or concerns, outside of those previously raised and mitigated in the IFU, were found. All clinical experts confirmed the testing and outputs were applicable to real life situations and could be used to effectively execute a planned cranial procedure, whether it be in pediatric patients or adult patients.

Clinical Evaluation

Clinical studies and findings found in peer-reviewed literature show the potential benefits associated with the use of the subject device outweigh the potential risks associated with its use. Scientific peer-reviewed publications describing the safe and effective application of virtual surgical planning in pediatric and adult patients are provided within this submission.

Conclusions

The KLS Martin IPS Planning System has the same intended use and similar technological characteristics as the predicate device. Technological differences have been addressed through performance data from the predicate and reference devices, in addition to validated simulated use testing and analysis of peer-reviewed clinical studies. All information provided show the safe and effective use of the subject device for the intended patient population.

In conclusion, the potential benefits associated with the use of the subject device outweigh its potential risks for the targeted patient population. According to the comparison based on the requirements of 21 CFR 807.87 and the information provided herein, it is concluded that the information included in this submission supports substantial equivalence.