July 8, 2022

KLS-Martin L.P.
Susan Leander
Regulatory Affairs Project Supervisor
11201 Saint Johns Industrial Parkway S
Jacksonville, Florida 32246

Re: K210228
Trade/Device Name: KLS Martin IPS Preprosthetic
Regulation Number: 21 CFR 872.3645
Regulation Name: Subperiosteal Implant Material
Regulatory Class: Class II
Product Code: ELE
Dated: June 1, 2022
Received: June 7, 2022

Dear Susan Leander:

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,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K210228

Device Name

KLS Martin IPS Preprosthetic

Indications for Use *(Describe)*

The KLS Martin IPS Preprosthetic Implant is a subperiosteal implant composed of titanium intended to construct patient specific prosthetic devices which are surgically implanted into the lower or upper jaw between the periosteum (connective tissue covering the bone) and supporting bony structures. The device is intended to provide support for multi-unit prostheses, such as dentures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

KLS martin L.P.
11201 Saint Johns Industrial Pkwy S • Jacksonville, FL 32246
Phone: 904-641-7746 • 800-625-1557 • Fax: 904-641-7378
www.klsmartinnorthamerica.com

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:	Susan Leander Regulatory Affairs Project Supervisor Phone: 800-625-1557 Email: susan.leander@klsmartin.com
Alternate Contact:	Melissa Bachorski Assistant Director RA/QMS Phone: 800-625-1557 Email: melissa.bachorski@klsmartin.com
Date Prepared:	July 7, 2022
Trade Name:	KLS Martin IPS Preprosthetic
Common Name:	Dental implant
Classification Name:	Implant, subperiosteal (21 CFR 872.3645)
Regulatory Class:	II
Product Code:	ELE
Predicate Device:	Hollow Basket Titanium Dental Implant **(K801208)**
Reference Devices:	Pacific Implants Intraosseous Dental Implant **(K813227)** KLS Martin Individual Patient Solutions **(K191028)**

Device Description

The KLS Martin Individual Patient Solutions (IPS) Preprosthetic system is comprised of patient-specific models and metallic bone plates with integrated pillars used in conjunction with metallic bone screws for internal fixation of the implant to maxillofacial / midface and mandibular bones. The integrated pillars will serve as the base for temporary dentures as well as a permanent prosthesis. The devices are manufactured based on medical imaging (CT scan) of the patient's anatomy with input from the physician during virtual planning and prior to finalization and production of the device. The physician only provides input for model manipulation and interactive feedback by viewing digital models of planned outputs that are modified by trained KLS Martin engineers during the planning session. For each design iteration, verification is performed by virtually fitting the generated implant over a 3D model of the patient's anatomy to ensure its dimensional properties allow an adequate fit.

The KLS Martin IPS Planning System is utilized to plan and design the IPS Preprosthetic implant. The 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, implants, and case reports.

Implants are provided non-sterile, range in thickness from 1.2 – 10.0 mm, and are manufactured using additive methods from Ti-6Al-4V (ASTM F136). These patient-specific devices are fixated with previously cleared KLS Martin screws.

Implants have a minimum of two (2) transgingival pillars for the attachment of dental prostheses. The straight pillars (0° to the occlusal plane) have a diameter of 4 mm and are provided at lengths up to 20 mm.

Indications for Use

The KLS Martin IPS Preprosthetic Implant is a subperiosteal implant composed of titanium intended to construct patient specific prosthetic devices which are surgically implanted into the lower or upper jaw between the periosteum (connective tissue covering the bone) and supporting bony structures. The device is intended to provide support for of multi-unit prostheses, such as dentures.

Technological Characteristics & Substantial Equivalence Discussion

The intended use of the subject device, KLS Martin IPS Preprosthetic is similar to the predicate device, K801208 and the reference device, K813227. The potential impact on substantial equivalence of each technological difference was addressed through risk analysis and verification and validation testing.

Similarities to Predicate

The subject and predicate devices are intended to be used to provide support for prosthetic devices. Both are subperiosteal implants made of titanium that are surgically placed in the upper or lower jaw to support prostheses. Both devices have transgingival pillars for the attachment of prostheses.

The subject and predicate devices are safe and effective at restoring a patient's chewing function when the maxilla and/or mandible have been compromised.

The subject device is provided non-sterile and requires the end-user to process the implants using validated cleaning and sterilization methods prior to use as recommended in the labeling. Sterilization information is not available for the predicate device.

Differences from Predicate

The subject and predicate devices are attached to the bony substructures of the jaw. The predicate device is an intraosseous implant whereas the subject device is implanted using bone screws to attach the device to the bone. Although attachment to the bone is achieved differently, both are effective methods. Studies of the predicate device present evidence of osseointegration that results in stable attachment of the implant. The attachment method used by the subject device has been safely and effectively demonstrated in more than one hundred clinical cases in the EU, where the device is currently marketed. Real-world evidence of the subject device's safe and effective use is cited in peer-reviewed literature.

KLS martin L.P.
11201 Saint Johns Industrial Pkwy S • Jacksonville, FL 32246
Phone: 904-641-7746 • 800-625-1557 • Fax: 904-641-7378
www.klsmartinnorthamerica.com

Reference Devices

KLS Martin Individual Patient Solutions (K191028), included as a reference device, is comprised of patient-specific models and metallic bone plates used in conjunction with metallic bone screws for internal fixation of maxillofacial / midface and mandibular bones.

Both the subject and reference devices are manufactured based on medical imaging (CT scan) of the patient's anatomy with input from the physician during virtual planning and prior to finalization and production of the device. The physician only provides input for model manipulation and interactive feedback by viewing digital models of planned outputs that are modified by trained KLS Martin engineers during the planning session. For each design iteration, verification is performed by virtually fitting the generated implant over a 3D model of the patient's anatomy to ensure its dimensional properties allow an adequate fit.

Subject and reference device implants are provided non-sterile and are manufactured using additive methods from Ti-6Al-4V. These patient-specific devices are fixated with previously cleared KLS Martin screws.

The Pacific Implant, Inc. Endosseous Dental Implant (K813227) has been included as a reference device for comparison of typical loading values for dental implants. The subject and reference devices are intended to be used to provide support for prosthetic devices. Both are made of titanium; both are surgically placed in the upper or lower jaw and both are devices to support prostheses. Both devices have transgingival pillars for the attachment of prostheses. Both devices are designed for use in patients that have sub-optimal quantity or quality of bone in the upper or lower jaw.

Both the subject and reference devices are safe and effective at restoring a patient's chewing function when the jawbone has been compromised.

The subject and reference devices are provided non-sterile and require the end-user to process the implants using validated cleaning and sterilization methods prior to use as recommended in the labeling.

KLS martin L.P.

11201 Saint Johns Industrial Pkwy S • Jacksonville, FL 32246
Phone: 904-641-7746 • 800-625-1557 • Fax: 904-641-7378
www.klsmartinnorthamerica.com

Device Comparison Table

	KLS Martin IPS Preprosthetic K210228 (Subject Device)	Hollow Basket Titanium Dental Implants K801208 (Primary Predicate)	Pacific Implant, Inc. Intraosseous Dental Implant K813227 (Reference Device)	KLS Martin Individual Patient Solutions K191028 (Reference Device)
Indications for Use	The KLS Martin IPS Preprosthetic Implant is a subperiosteal implant composed of titanium intended to construct patient specific prosthetic devices which are surgically implanted into the lower or upper jaw between the periosteum (connective tissue covering the bone) and supporting bony structures. The device is intended to provide support for multi-unit prostheses, such as dentures.	The Hollow Basket Titanium Dental Implant is a subperiosteal implant composed of titanium intended to construct patient specific prosthetic devices which are surgically implanted into the lower or upper jaw between the periosteum (connective tissue covering the bone) and supporting bony structures.	An endosseous dental implant is a prescription device made of a material such as titanium or titanium alloy that is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.[1]	The KLS Martin Individual Patient Solutions implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions.
Contraindications	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 severe 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 13. Failure to locate a primary nerve in the lower jaw 14. Uncontrolled Type II diabetes 15. Oral or intravenous bisphosphonates 16. Bruxism (tooth grinding or clenching) 17. Smoking	Unknown – similar to K813227	1. Local tissue or existing dentition degeneration due to[2]: a. Excessive mobility b. Loss of integration c. Incompatibility of the device components d. Structural failure of the device 2. Pain 3. Infection 4. Adverse tissue reaction 5. Bone or nerve damage a. Sinus perforation b. Alveolar plate perforation c. Transient or chronic pain/facial paresis 6. Migration or thermal injury a. Incompatibility with MRI 7. Patient Selection Criteria a. Previous radiation therapy (affects bone quality)	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] 21 CFR 872.3640 https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=872.3640
[2] https://wayback.archive-it.org/7993/20170405193222/https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/DentalProductsPanel/ucm360925.htm

KLS martin L.P.

11201 Saint Johns Industrial Pkwy S • Jacksonville, FL 32246
Phone: 904-641-7746 • 800-625-1557 • Fax: 904-641-7378
www.klsmartinnorthamerica.com

Patient-specific?	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.	No.	No.	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.
Classification	21 CFR 872.3645 Class II	21 CFR 872.3645 Class II	21 CFR 872.3640 Class II	21 CFR 872.4760 Class II
Product Code	ELE	ELE	DZE	JEY
Material	• Anatomical Models: Epoxy/Acrylic Resins • Implants: Ti-6Al-4V	• Implants: Titanium	• Implants: CP Titanium	• Anatomical Models: Epoxy/Acrylic Resins • Cutting/Marking Guides: Polyamide, Ti-6Al-4V, CP Titanium • Splints: acrylic/methacrylic resins
Manufacturing Method	• Epoxy/Acrylic Resins: Stereolithography (SLA) • Ti-6Al-4V: 3D (Additive; Selective Laser Melting)	• Traditional milling	• Traditional milling/stamping	• Epoxy/Acrylic Resins: Stereolithography (SLA) • CP Titanium: Traditional (Subtractive) • Ti-6Al-4V: 3D (Additive; Selective Laser Melting) • Polyamide: 3D (Additive; Selective Laser Sintering)
Sterilization	Non-sterile	Unknown	Non-sterile	Non-sterile
Anatomical Sites	Maxillofacial/Midface & Mandible	Maxillofacial/Midface & Mandible	Mandible	Maxillofacial / Midface & Mandible
Plate Specifications				
Thickness	1.2 mm – 10.0 mm	Unknown	2.0 mm	• Orbital floor only: 0.3 mm – 1.0 mm • Maxillofacial / midface reconstruction: 0.6 mm – 10.0 mm • Mandibular reconstruction: 1.0 mm – 3.0 mm
Style	Non-locking Compression Threaded	One-piece hollow, grooved, bore-holed cylinders with upper portions designed to support an artificial denture	One-piece U-shaped bar has upper and lower edges and is arranged to support an artificial denture on its upper edge	Non-locking Compression Threaded
Width (between screws)	Min: 4.5 mm	No screws are used with this device	No screws are used with this device	<u>Maxillofacial / midface:</u> Min: ≥ 4.5 mm (around screw holes) Min: ≥ 3 mm (not around screw hole) Max: Dependent on screw-hole <u>Mandibular:</u> Min: 7 mm Max: 8.5 mm
Length	<u>Maxillofacial / midface:</u> Min: 29 mm Max: 320 mm <u>Mandibular:</u> Min: 29 mm Max: 320 mm	Unknown	Curved front portion: 97.0 mm – 110.0 mm	<u>Maxillofacial / midface:</u> Min: 18 mm Max: 350 mm <u>Mandibular:</u> Min: 31 mm Max: 320 mm

KLS martin L.P.
11201 Saint Johns Industrial Pkwy S • Jacksonville, FL 32246
Phone: 904-641-7746 • 800-625-1557 • Fax: 904-641-7378
www.klsmartinnorthamerica.com

Width around Screws	1.5 System: ≥ 4.5 mm 2.0/2.3 System: ≥ 6.5 mm 2.7 System: ≥ 8 mm	No screws are used with this device	No screws are used with this device	1.5 System: ≥ 4.5 mm 2.0/2.3 System: ≥ 6.5 mm 2.7 System: ≥ 8 mm
Number of Screw Holes	Maxillofacial / midface: Min: 4 per side of defect Max: Dependent on length & hole spacing Mandibular: Min: 4 Max: Dependent on length & hole spacing	Holes are present but are not screw holes. These are to allow for bone ingrowth.	14 holes are present but are not screw holes. These are to allow for bone ingrowth.	Maxillofacial / midface: Min: ≥ 2 per side of defect Max: Dependent on length & hole spacing Mandibular: Min: 4 Max: Dependent on length & hole spacing
Pillar Diameter	≥ 4 mm	Unknown	N/A	N/A
Angulation of Pillar to the Occlusal Plane	0°	Unknown	N/A	N/A

Screw Specifications				
Screw Diameter	1.5 mm – 3.2 mm	Not applicable	Not applicable	Maxillofacial / midface 1.5 mm – 2.3 mm Mandibular: 2.0 mm – 3.2 mm
Screw Length	3.5 mm – 21 mm	Not applicable	Not applicable	Maxillofacial / midface 3.5 mm – 22 mm Mandibular: 5 mm – 22 mm
Screw Style	maxDrive (Drill-Free, locking, [ThreadLock Taper Screw – TLTS])	Not applicable	Not applicable	maxDrive & crossDrive (Drill-Free, locking [ThreadLock Taper Screw -TLTS])

KLS martin L.P.
11201 Saint Johns Industrial Pkwy S • Jacksonville, FL 32246
Phone: 904-641-7746 • 800-625-1557 • Fax: 904-641-7378
www.klsmartinnorthamerica.com

Performance Testing – Non-clinical

MR Conditional Labeling

Non-clinical worst-case MRI review was performed to evaluate the metallic IPS Preprosthetic devices in the MRI environment using scientific rationale and published literature (e.g., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system including all variations (dental implants and fixation screws) and material compositions. The rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment", including magnetically induced displacement force and torque.

Additive Manufacturing Build Orientation & Location

Baseline Study – Build Orientation (#PBN-0478)

A baseline study was conducted to demonstrate that placement on the bed has minimal impact on the final component in terms of dimensional accuracy from the build.

Fourteen (14) Selective Laser Melting (SLM) test articles, identical to the final finished device with regard to processing, were used to examine the influence of various bed positions and any effect of component dimensional accuracy using FEM analysis. The results indicate that components placed centrally vs. peripherally have minor impact on the final component.

Position and Tensile Strength (#PBN-0481)

Additional studies were performed to determine whether build location in the build space has a significant effect on device characteristics or performance. The baseline study performed on the SLM test articles demonstrates that the components achieved a tensile strength of 860 N/mm^2 and component position does not significantly impact tensile strength.

SLM Orientation and Tensile Strength (#PBN-0474)

Various component orientations (Z, 45° tilted, 45° horizontal, Y, and X) were evaluated to ensure the SLM test articles met the 860 N/mm^2 requirement for tensile strength in accordance with ASTM F136. All test setups rendered similar values for the various orientations tested, which exceeded the 860 N/mm^2 requirement for tensile strength per ASTM F136.

Dimensional Evaluation of Worst-Case Model (#IRN-0004)

A full validation to address a worst-case design of the subject device in terms of the accuracy of the final device as compared to the initial software model design was performed. An evaluation of a worst-case implant device was evaluated using a 3D scanner to determine the dimensions of each manufactured part. An STL of the scanned part was created and compared against the original software model design. The test report results show that deviations of the manufactured part versus the associated original model design file are well within the acceptance criteria. All samples passed the acceptance criteria of deviation relative to nominal part by not exceeding the maximum tolerance of ±1.5 mm. These results indicate that Ti-6AL-4V parts manufactured implants within their specification range meet dimensional requirements for fit and function of the devices as defined by the model.

11201 Saint Johns Industrial Pkwy S • Jacksonville, FL 32246
Phone: 904-641-7746 • 800-625-1557 • Fax: 904-641-7378
www.klsmartinnorthamerica.com

Material Characterization

Powder Recycling Process and Evaluation of Device Performance (#PBN-0484)

An assessment of the material recycling protocol was conducted to determine the effect of material recycling on the properties of the final finished device. The analysis demonstrated the material recycling process, tested with 256 SLM test articles over the course of one year, yielded consistent tensile strength results.

Biocompatibility Testing

Biocompatibility endpoints were evaluated in accordance with ISO 10993. The battery of cytotoxicity, chemical analysis, sensitization and irritation, and chemical/material characterization testing was leveraged from the reference device, KLS Individual Patient Solutions (K191028), for titanium devices. The subject device is identical to the reference device in final finished form, which includes material formulations, manufacturing methods and processes, and sterilization methods. No other chemicals have been added (e.g., fillers, additives, cleaning agents). Therefore, this adequately addresses biocompatibility for the subject device system.

Sterilization Testing

Steam sterilization validations were performed using the dynamic-air-removal cycle in accordance with AAMI ANSI ISO 17665-1 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 titanium were leveraged from the reference device, KLS Martin Individual Patient Solutions (K191028). Subject titanium devices are identical in formulation, manufacturing processes, and post-processing procedures (cleaning & sterilization) as the reference device.

Pyrogenicity Testing

LAL endotoxin testing was conducted according to AAMI ANSI ST72 to address the presence of bacterial endotoxins and ensure they meet pyrogen limit specifications. The results of the testing demonstrate that the subject devices contain endotoxin levels below the USP allowed limit for medical devices and meet pyrogen limit specifications. LAL endotoxin testing for titanium was leveraged from the predicate device, KLS Martin Individual Patient Solutions (K191028). Subject titanium devices are identical in formulation, manufacturing processes, and post-processing procedures (cleaning & sterilization) as the reference device.

Software Verification and Validation

Software verification and validation was performed on individual software applications that are used in the planning and design of the implant based on 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.

KLS martin L.P.
11201 Saint Johns Industrial Pkwy S • Jacksonville, FL 32246
Phone: 904-641-7746 • 800-625-1557 • Fax: 904-641-7378
www.klsmartinnorthamerica.com

Performance Testing – Clinical

Clinical testing data of IPS Preprosthetic was collected up to 74 months post-operatively which evaluated 39 total implants from 35 patients. The data consisted of 19 patients who received implants due to postablative maxillary defects, 10 patients who received implants to treat a severely atrophic maxilla, and 6 patients who were treated for a cleft lip and palate (CLP) deformity with significant soft and hard tissue impairment. Of the 39 implants, there were no instances of implant loosening (0%) or a removed implant (0%). There was one instance of a reduced post (2.9%), 3 instances of exposed/removed screws (8.6%), 3 instances of infections/abscesses (8.6%), and 14 instances of a partial exposure of underlying framework (40%).

Substantial Equivalence Conclusion

KLS Martin IPS Preprosthetic has the same intended use, same fundamental principles of operation, and similar technological features compared to the predicate device. Any differences in technological features between the subject and predicate devices do not raise different questions of safety and effectiveness.