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

8/11/22

Re: K220050
Trade/Device Name: KLS Martin IPS Distraction
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: MQN
Dated: June 30, 2022
Received: July 12, 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,

for Andrew 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220050

Device Name
KLS Martin IPS Distraction

Indications for Use *(Describe)*
KLS Martin IPS Distraction includes devices intended as bone stabilizers and lengthening (and or transport) devices for correction of congenital deficiencies or post traumatic defects of the mandible (including ramus, body, alveolar ridge, palate, and symphysis) and mid-face bones that require gradual distraction in adults, adolescents, children and infants weighing more than 2.5 kg.

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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K220050

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 Manager Phone: 800-625-1557 Email: susan.leander@klsmartin.com
Date Prepared:	August 11, 2022
Trade Name:	KLS Martin IPS Distraction
Common Name:	Plate, Bone
Classification Name:	Bone Plate
Regulatory Class:	II
Product Code:	MQN
Primary Predicate:	KLS Martin Internal Distraction – Sterile **(K161470)**
Reference Devices:	KLS Martin Individual Patient Solutions **(K191028)** KLS Martin Zurich Distraction System (**K010139**)

Device Description

KLS Martin IPS Distraction System is comprised of patient-specific models, guides and distraction footplates used in conjunction with previously cleared distractor bodies and metallic bone screws for internal fixation and reconstruction of maxillofacial / midface and mandibular bones. 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 personnel during the planning session. For each design iteration, verification is performed by virtually fitting the generated device model over a 3D model of the patient's anatomy to ensure its dimensional properties allow an adequate fit.

Implants are provided sterile or non-sterile, range in thickness from 0.6 – 10 mm, and are manufactured using additive or traditional (subtractive) methods from either CP Titanium (ASTM F67) or Ti-6Al-4V (ASTM F136) materials. These patient-specific devices are fixated with previously cleared KLS Martin screws.

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Indications for Use

KLS Martin IPS Distraction includes devices intended as bone stabilizers and lengthening (and or transport) devices for correction of congenital deficiencies or post traumatic defects of the mandible (including ramus, body, alveolar ridge, palate, and symphysis) and mid-face bones that require gradual distraction in adults, adolescents, children, and infants weighing more than 2.5 kg.

Technological Characteristics & Substantial Equivalence Discussion

The intended use and technological characteristics of the subject device, KLS Martin IPS Distraction are the same as those of the predicate device, KLS Martin Internal Sterile Distraction, cleared under K161470. Both are distraction devices made of titanium. Both use standard distractors with attached footplates. The potential impact on substantial equivalence of each technological difference was addressed through risk analysis and verification and validation testing.

Similarities to Predicate and Reference Devices

The primary predicate device, KLS Martin Internal Sterile Distraction, K161470, and the subject device, KLS Martin IPS Distraction are intended for gradual distraction in the facial skeleton and share the same fundamental principle of operation – metallic bone plates used in conjunction with metallic bone screws for bone stabilization and lengthening of bones. The indications for use for the subject device are the same as the predicate device. The skeletal regions for use for the subject and predicate devices are similar.

Both the primary predicate device and the KLS Martin Zurich Distraction System reference device, cleared under K010139, present evidence of substantially equivalent use of similar devices. The method to attach the patient-specific footplates to the distraction bodies is the same for the subject, predicate and reference devices.

The KLS Martin IPS Distraction devices are provided sterile (same as K161470) or non-sterile (same as K010139 and K191028). The non-sterile devices require the end-user to process them using validated cleaning and sterilization methods prior to use as recommended in the labeling.

The KLS Martin Individual Patient Solutions is included as a reference device to support the use of patient-specific metallic implants. Both the subject and the KLS Martin Individual Patient Solutions (K191028) reference devices use image data obtained from medical scanners, such as a CT scan. They both use validated commercial-off-the-shelf (COTS) software applications to transfer patient imaging from a DICOM format to an .STL format and manipulate the images to produce a final design file.

The manufacturing materials used for the implants in the subject device are similar to those cleared in their own prior clearance, K191028. The design and dimensions of the plates will be based on patient-specific data, using similar methods described in K191028, made from either CP Titanium (ASTM F67) or Ti-6Al-4V (ASTM F136) using traditional (subtractive) or additive manufacturing methods. The bone plates are similar in final finished form to those presented in the K191028 reference device, and therefore performance and biocompatibility are adequately addressed.

IPS Distractor bone plates will be attached to maxillofacial, midface or mandibular bones and to distractor bodies for distraction osteogenesis. Bone plates in the subject device may be implanted permanently in skeletally mature patients or they may be removed on completion of the procedure, as is common for K161470 and K010139 predicate and reference devices. Permanent implants are not recommended for use in skeletally immature patients (16 years of age or younger).

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Differences from Predicate and Reference Devices

The indications for use statements for the subject device and predicate devices are the same, except the subject device statement specifically lists the following targeted patient populations:

- Infants that weigh more than 2.5 kg (29 days to < 2 years of age) *
- Children (2 years of age to < 12 years of age)
- Adolescents (12 years of age – 21 years of age)
- Adults

***Premature neonates are not included in the proposed target population. The lowest patient weight for the subject device is 2.5 kg (5 pounds, 8 ounces), which is considered normal weight at delivery.**

A risk assessment has been performed based on FDA guidance, "Premarket Assessment of Pediatric Medical Devices, March 24, 2014" for these pediatric subpopulations with supporting peer-reviewed clinical literature to demonstrate the safety and effectiveness of the subject device implants for use in the target pediatric subpopulations.

The reference device, K191028, was previously cleared only for the adult population, but the primary predicate, K161470, supports the use of implants in pediatric subpopulations infant, children, and adolescents.

The KLS Martin IPS Distraction titanium alloy footplates are attached to titanium alloy distraction bodies, whereas the predicate and reference device CP titanium footplates are attached to the same style titanium alloy distraction bodies. The different material combinations were addressed through performance testing.

Previously cleared specifications for the K191028 reference device plate thicknesses range from 0.3 mm – 10 mm and are fixated with previously cleared KLS Martin titanium screws ranging in diameter from 1.0 mm – 3.2 mm in lengths from 3.5 mm – 22 mm. The subject device plates range in thickness from 0.6 mm – 10 mm and are fixated with previously cleared KLS Martin titanium screws ranging in diameter from 1.0 mm – 2.3 mm in lengths from 3 mm – 22 mm. The screw dimensions for the subject device are similar to those previously evaluated in K161470. The predicate and reference device dimensions encompass the entire range of dimensions for the subject device.

A device comparison table of the subject, predicate, and reference devices is presented, below.

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Device Comparison Table

	KLS Martin IPS Distraction (Subject Device)	KLS Martin Internal Distraction - Sterile K161470 (Primary Predicate)	KLS Martin Individual Patient Solutions K191028 (Reference Device)	KLS Martin Zurich Distraction System K010139 (Reference Device)
Indications for Use	KLS Martin IPS Distraction includes devices intended as bone stabilizers and lengthening (and or transport) devices for correction of congenital deficiencies or post traumatic defects of the mandible (including ramus, body, alveolar ridge, palate, and symphysis) and mid-face bones that require gradual distraction in adults, adolescents, children and infants weighing more than 2.5 kg.	Internal Distraction - Sterile includes devices intended as bone stabilizers and lengthening (and or transport) devices for correction of congenital deficiencies or post traumatic defects of the mandible (including ramus, body, alveolar ridge, palate, and symphysis) and mid-face bones that require gradual distraction.	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.	The Zurich Distraction System includes devices intended as a bone stabilizer and lengthening (and or transport) device when correction of congenital deficiencies or post traumatic defects of the mandible (including ramus, body, alveolar ridge, palate, symphysis), mid-face, and cranial bones require gradual distraction.
Contraindications	1. Active infection 2. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone or latent infections 3. Patients with mental or neuralgic conditions who are unwilling or incapable of following postoperative care instructions 4. Foreign body sensitivity- where material sensitivity is suspected, tests are to be made prior to implantation	1. Active infection 2. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone or latent infections 3. Patients with mental or neuralgic conditions who are unwilling or incapable of following postoperative care instructions 4. Foreign body sensitivity- where material sensitivity is suspected, tests are to be made prior to implantation	1. 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. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone or latent infections 3. Patients with mental or neuralgic conditions who are unwilling or incapable of following postoperative care instructions 4. Foreign body sensitivity- where material sensitivity is suspected, tests are to be made prior to implantation 5. For Symphysis: In those patients where there is inadequate volume or quality of bone to place the distractor securely. 6. For Ramus: In these cases where is an inadequate volume or quality of bone to place the distractor securely.

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Device Comparison Table

	KLS Martin IPS Distraction	KLS Martin Internal Distraction - Sterile K161470	KLS Martin Individual Patient Solutions K191028	KLS Martin Zurich Distraction System K010139
	(Subject Device)	**(Primary Predicate)**	**(Reference Device)**	**(Reference Device)**
Patient-specific?	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.	No. Standard distraction plates are available in a variety of sizes in thicknesses of 0.6 mm – 2.0 mm.	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.	No. Standard distraction plates are available in a variety of sizes in thicknesses of 0.6 mm – 1.0 mm.
Classification	21 CFR 872.4760, Class II	21 CFR 872.4760, Class II	21 CFR 872.4760, Class II	21 CFR 872.4760, Class II
Product Code	MQN	MQN	JEY	MQN
Material	Anatomical Models: Epoxy/Acrylic Resins Implants: CP Titanium or Ti-6Al-4V	Implants: CP Titanium or Ti-6Al-4V	Anatomical Models: Epoxy/Acrylic Resins Implants: CP Titanium or Ti-6Al-4V	Traditional (Subtractive) and Ti-6Al-4V: Traditional (Subtractive)
Manufacturing Method	Epoxy/Acrylic Resins: Stereolithography (SLA) CP Titanium or Ti-6Al-4V: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; Selective Laser Melting)	Traditional (Subtractive) and Ti-6Al-4V: Traditional (Subtractive)	Epoxy/Acrylic Resins: Stereolithography (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: 3D (Additive; Selective Laser Melting)	Traditional (Subtractive) and Ti-6Al-4V: Traditional (Subtractive)
Sterilization	Sterile (Gamma) Non-sterile (Steam)	Sterile (Gamma Radiation)	Non-sterile (Steam)	Non-sterile (Steam)
Anatomical Sites	Maxillofacial / Midface & Mandible	Maxillofacial / Mandible	Maxillofacial / Midface & Mandible	Maxillofacial / Mandible
Patient Population	• Infants that weigh at least 2.5kg (29 days to <2 years of age) • Children (2 years of age to < 12 years of age) • Adolescents (12 years of age – 21 years of age) • Adults	• Infants (29 days to < 2 years of age) • Children (2 years of age to < 12 years of age) • Adolescents (12 years of age – 21 years of age) • Adults	Adult	Pediatric & Adult
Distraction Length	Max 60 mm	Max 60 mm	Not specified	15mm – 50 mm

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Device Comparison Table				
	KLS Martin IPS Distraction	**KLS Martin Internal Distraction - Sterile K161470**	**KLS Martin Individual Patient Solutions K191028**	**KLS Martin Zurich Distraction System K010139**
	(Subject Device)	**(Primary Predicate)**	**(Reference Device)**	**(Reference Device)**
Plate Specifications				
Thickness	• 0.6mm-10mm	• 0.6mm-2.0mm	• Orbital floor only: 0.3mm–1.0mm • Maxillofacial / midface reconstruction: 0.6mm–10 mm • Mandibular reconstruction: 1.0mm–3.0mm	• 0.6mm-1.0mm
Plate Style	Locking & non-locking	Locking & non-locking	Locking & non-locking	Locking & non-locking
Plate Width	Maxillofacial / midface /mandibular: Min: ≥ 3 mm Max: Dependent on screw-hole	Not specified	Maxillofacial / midface: Min: ≥ 3 mm Max: Dependent on screw-hole Mandibular: Min: ≥ 7 mm Max: 8.5 mm	Not specified
Plate Length	Maxillofacial / midface /mandibular: Min: 5 mm Max: 350 mm	Not specified	Maxillofacial / midface: Min: 18 mm Max: 350 mm Mandibular: Min: 31 mm Max: 320 mm	Not specified
Degree of Curvature	In-plane Min: 30° Max: 180° Out-of-plane Min: 15° Max: 180°	Not specified	In-plane Min: 30° Max: 180° Out-of-plane Min: 15° Max: 180°	Not specified

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Device Comparison Table				
	KLS Martin IPS Distraction	**KLS Martin Internal Distraction - Sterile K161470**	**KLS Martin Individual Patient Solutions K191028**	**KLS Martin Zurich Distraction System K010139**
	(Subject Device)	**(Primary Predicate)**	**(Reference Device)**	**(Reference Device)**
Number of Holes	Min: ≥ 2 per side of defect Max: Dependent on length & hole spacing	Not specified	Maxillofacial / midface: Min: ≥ 2 per side of defect Max: Dependent on length & hole spacing Mandibular: Min: ≥ 4 Max: Dependent on length & hole spacing	Not specified
Hole Spacing	Min: ≥ 2.3 mm	Min: ≥ 2.3 mm	Maxillofacial /midface: ≥ 4.5 mm Mandibular: ≥ 8 mm	Min: ≥ 2.3 mm
Screw Specifications				
Screw Diameter	1.0 mm – 2.3 mm	1.0 mm – 3.2 mm	Maxillofacial / midface 1.0 mm - 2.3 mm Mandibular: 2.0 mm - 3.2 mm	1.5 mm – 2.7 mm
Screw Length	3 mm – 22 mm	2 mm – 22 mm	Maxillofacial / midface 3.5 mm - 22 mm Mandibular: 5 mm - 22 mm	4 mm – 22 mm

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Performance Testing – Non-clinical

Performance Testing

Performance testing was completed to demonstrate substantial equivalence of the subject device to the predicate and reference devices.

A direct comparison weld strength test was performed to address the difference in material combinations (titanium alloy/titanium alloy connection vs. CP titanium/titanium alloy connection) used for the subject versus predicate/reference devices, respectively. The titanium alloy/titanium alloy material combination was able to withstand a greater tensile load than the CP titanium/titanium alloy material combination.

Additional performance testing presented in K191028 and equally relevant to the subject device, was conducted in accordance with the device testing considerations outlined in *Technical Considerations for Additive Manufactured Medical Devices*, issued December 5, 2017.

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 K191028 for titanium devices. The subject devices are similar to the reference devices in final finished form, including 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

KLS Martin IPS Distraction implants are provided sterile or non-sterile. Models are provided non-sterile. Models and non-sterile implants are to be cleaned and sterilized by the end user before use. Validated cleaning and sterilization methods are provided in the instructions for use to the end user.

Steam sterilization validations were performed using 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 titanium were leveraged from the reference device, KLS Martin Individual Patient Solutions (K191028). Subject titanium devices are similar in formulation, manufacturing processes, and post-processing procedures (cleaning & sterilization) as the reference device.

Pyrogenicity Testing

As part of the sterilization validation, LAL endotoxin testing was conducted according to AAMI ANSI ST72:2019 to address the presence of bacterial endotoxins and ensure the devices 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 reference device, KLS Martin Individual Patient Solutions (K191028). Subject titanium devices are similar 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 each individual software application that is used in the planning and design of the patient's images (CT). Quality and on-site user acceptance testing provide objective evidence that all software requirements and specifications were implemented correctly and completely and are traceable to system requirements. Testing required resulting from risk analysis and impact assessments showed conformity with pre-defined specifications and acceptance criteria.

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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.

Performance Testing – Clinical

Risk mitigation assessments have been completed based on FDA guidance, *"Premarket Assessment of Pediatric Medical Devices,"* issued March 24, 2014, to demonstrate the safety and effectiveness for use of the IPS output devices in the pediatric population. These risk assessments evaluated the following risk factors for pediatric patients: age, size, growth and development, body habitus, developmental milestones, pathophysiology, behavioral factors, psychosocial factors, human factors, surgical factors, and cumulative effects from repeat or unplanned radiation exposure (i.e., CT scan).

The short-term and long-term mitigations for both children and adolescents are similar with regard to implantation. The size of the implant will be dictated by the patient's anatomy and the approving medical practitioner. Assuming no physes are violated when placing the implant, there are no short-term concerns when placing the patient-specific implant. The most challenging long-term impact for both subpopulations is use of permanent implants in a growing patient. There is a possibility that an implant may restrict growth and development when implanted into a maturing individual. Permanent implants should not be used in patients that are skeletally immature, specifically in patients less than 16 years of age. Caution should be taken when considering permanent implant placement in any patient with potential for continued facial growth.

Unplanned or repeat radiation exposure prior to or following the pediatric patient's initial surgery is a risk that is mitigated by device labeling to include special considerations for pediatric populations to minimize ionizing radiation by using low-dose and child-size CT scan protocols when deemed appropriate based on patient size, weight, height, and clinical needs.

To demonstrate clinical performance of KLS Martin IPS implants in the pediatric subpopulations of infants (weighing more than 2.5 kg), children, and adolescents (29 days through 21 years of age), 5 clinical studies including patients 26 days of age through 21 years of age, were analyzed:

	Doscher, et al (2014)	**Gray, et al (2017)**	**Steinbacher (2015)**	**Resnick (2017)**	**Meena, et al (2017)**
Patient age	26 days	3 – 17 years	<1 month – 21+ years	Infants	
Patient Population	Neonate	Children & Adolescents	Neonates, Infants, Children & Adults	Infants	
Treatment	CT-based patient-specific surgical planning for mandibular distraction osteogenesis (DO)	Virtual Surgical Planning (VSP) using CT scans and CAD/CAM technology in craniofacial reconstructive surgeries	3D analysis and surgical planning in craniomaxillofacial surgeries using CT scan data	Mandibular distraction osteogenesis in infants with Robin sequence	Development of a custom zygomatic implant using metal sintering

Based on published literature findings of the subject device and similar bone plate devices and the results from the risk analysis, it can be concluded that the subject device can be used for the treatment of infants (weighing more than 2.5 kg), children, and adolescents (29 days through 21 years of age) if additional precautions are taken into account.

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Substantial Equivalence Conclusion

KLS Martin IPS Distraction footplates have the same intended use and technological characteristics as the predicate device. The indications for use for the subject device are the same as the predicate device with the exception of specifically calling out targeted patient populations. Testing to evaluate performance of the subject device demonstrates that any differences in technological characteristics do not alter the intended therapeutic outcomes and provides adequate comparison to the predicate and reference devices. Testing has demonstrated that any differences in technological characteristics do not raise new or different issues of safety or effectiveness and the information submitted supports substantial equivalence.