DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

KLS Martin LP
Gary Moore
Quality Management And Regulatory Affairs Manager
11201 Saint Johns Industrial Pkwy S
Jacksonville, Florida 32246

November 21, 2017

Re: K163579
Trade/Device Name: KLS Martin Individual Patient Solutions
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: October 20, 2017
Received: October 23, 2017

Dear Gary Moore:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mary S. Runner -S

for
Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163579

Device Name

KLS Martin Individual Patient Solutions

Indications for Use *(Describe)*

KLS Martin Individual Patient Solutions implant devices are intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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K163579

Section 5

510(k) Summary

21 CFR 807.92

Submitter:	KLS Martin LP 11201 Saint Johns Industrial Pkwy S Jacksonville, FL 32246
Contact Person:	Gary Moore Quality Management and Regulatory Affairs Manager Phone: 800-625-1557 Email: gmoore@klsmartin.com
Date Prepared:	November 20, 2017
Trade Name:	KLS Martin Individual Patient Solutions
Common Name:	Plate, Bone
Classification Name:	Bone plate (21 CFR 872.4760)
Regulatory Class:	II
Product Code:	JEY
Predicate Device:	KLS Martin Mandibular Reconstruction System II **(K032442)**
Reference Devices:	Patient Contoured Mesh **(K062570)** KLS Mini Osteosynthesis System **(K943347)** Centre-Drive Drill-Free Screw **(K971297)** KLS Martin Thoracic Plating System **(K153482)**
Device Description:	KLS Martin Individual Patient Solutions is comprised of patient-specific models and metallic bone plates used in conjunction with metallic bone screws for internal fixation of mandibular bone. 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 device model over a 3D model of the patient's anatomy to ensure its dimensional properties allow an adequate fit.

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Implants are provided non-sterile, range in thickness from 1.0 – 3.0 mm, and are manufactured using traditional (subtractive) or rapid prototyping (additive) 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.

Indications for Use: KLS Martin Individual Patient Solutions implant devices are intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.

Technological Characteristics & Substantial Equivalence Discussion

The intended use and technological characteristics of the subject device, KLS Martin Individual Patient Solutions, are either identical or have been demonstrated to be substantially equivalent to the primary predicate device, KLS Martin Mandibular Reconstruction System II (K032442):

The subject and primary predicate devices are intended for reconstructive surgery in the facial skeleton and share the same fundamental principle of operation – metallic plates used in conjunction with metallic screws for mandibular reconstructive surgery. The subject device of this submission is specific for mandibular fractures and reconstruction, which is identical to the predicate device (K032442), and similar to the reference device (K062570) cleared for use in the maxillofacial, mandibular, and craniofacial skeleton. Additional reference devices (K943347, K971297, and K153482) intended for bone fixation have been included to cover the range of screw characteristics described in this submission.

The design and materials used for the mandibular reconstruction plates in the subject device is similar to those cleared in KLS Martin Mandibular Reconstruction System II (K032442). The design and dimensions of the plates will be based on the patient-specific data, using similar methods described in Patient Contoured Mesh (K062570), made from either CP Titanium (ASTM F67) using traditional manufacturing methods or Ti-6Al-4V powder (ASTM F136) via additive, laser sintering manufacturing methods, and fall within previously cleared specifications for plate thicknesses ranging from 1.0 – 3.0 mm.

Plates will be fixated with previously cleared KLS Martin titanium screws ranging in diameter from 2.0 – 3.2 mm in lengths from 5 – 22 mm (K943347, K971297, K032442, and K153482). The screw characteristics (head style, type, range of size) have been cleared in the reference devices.

All devices are provided non-sterile for steam sterilization by the end-user.

The angles and dimensions of each KLS Martin Individual Implant Solutions implant devices is determined based on the patient anatomy and surgical plan and should not be further contoured intraoperatively, whereas the plates in the KLS Martin Mandibular Reconstruction System II (K032442) are angled and transversely pre-curved to follow the natural curves of the mandible, but are not designed based on patient specific data as described in the reference device K062570.

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Device Comparison Table						
	Individual Patient Solutions **(Subject Device)**	**KLS Martin Mandibular Reconstruction System II K032442** **(Primary Predicate)**	**Patient Contoured Mesh K062570** **(Reference Device)**	**KLS Mini Osteosynthesis System K943347** **(Reference Device)**	**Centre-Drive Drill-Free Screw K971297** **(Reference Device)**	**KLS Martin Thoracic Plating System K153482** **(Reference Device)**
Indications for Use	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 Mandibular Reconstruction System II is intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstruction.	Patient Contoured Mesh (PCM) is intended to replace bony voids in mandibular, maxillofacial, or craniofacial skeleton.	The device system has the same intended use as its predicate (K854886).	KLS Martin Centre-Drive Drill-Free Screws are intended for use in rigid internal fixation of the oral-maxillo-cranid-facial bones. The bone screws are used to anchor plates which are contoured to fit the bony surface and stabilize the bone fragments. The addition of the self drilling feature is the only difference between the submitted device and the predicate device referenced.	The KLS Martin Thoracic Plating 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.
Patient-specific configuration?	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.	No. Devices are provided in a standard shape and matched to the patient's anatomy intraoperatively.	Yes. Devices are manufactured patient-specific, based on a CT scan of the patient.	No. Devices are provided in a standard shape and matched to the patient's anatomy intraoperatively.	No. Devices are provided in a standard shape and matched to the patient's anatomy intraoperatively.	No. Devices are provided in a standard shape and matched to the patient's anatomy intraoperatively.
Classification	21 CFR 872.4760, Class II	21 CFR 872.4760, Class II	21 CFR 882.5330, Class II	21 CFR 872.4760, Class II	21 CFR 888.3030, Class II	21 CFR 888.3030, Class II

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Product Code	JEY	MQN	GXN	JEY	HRS	HRS
Material	CP Titanium or Ti-6Al-4V	CP Titanium or Ti-6Al-4V	CP Titanium or Ti-6Al-4V	Plates: CP Titanium Screws: Ti-6Al-4V	Ti-6Al-4V	CP Titanium and Ti-6Al-4V
Manufacturing Method	Traditional (Subtractive) 3D (Additive)	Traditional (Subtractive)	Traditional (Subtractive) 3D (Additive - Skull Models)	Traditional (Subtractive)	Traditional (Subtractive)	Traditional (Subtractive)
Sterilization	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam)	Non-sterile (Steam) or Sterile (gamma irradiation)
Anatomical Sites	Mandible	Mandible	Craniofacial, Maxillofacial, Mandibular	Craniofacial, Maxillofacial, Mandibular	Craniofacial, Maxillofacial, Mandibular	Thoracic
Plates						
Thickness	1.0 mm - 3.0 mm	1.0 mm - 3.0 mm	0.6 mm - 1.0 mm	0.6 - 1.0 mm	Not applicable	1.0 mm - 3.0 mm
Style	Non-compression Compression Threaded	Non-compression Compression Threaded	Mesh and solid with or without holes	Standard Low Profile	Not applicable	Sternal: Standard linear shapes (locking) Rib: Bi-linear, pre-contoured X-& Z-shaped (locking)
Width (screw-hole dependent)	Min: 7 mm Max: 8.5 mm	Min: 6 mm Max: 8 mm	Not applicable	Not applicable	Not applicable	Not applicable

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Length	Min: 31 mm Max: 320 mm	Min: 28.5 mm Max: 240.65 mm	Not applicable	Not applicable	Not applicable	Not applicable
Degree of curvature (in-plane)	Min: 90° Max: 180°	Min: 125° Max: 180°	Not applicable	Not applicable	Not applicable	Not applicable
Degree of curvature (out-of- plane)	Min: 60° Max: 180°	Min: N/A Max: 180°	Not applicable	Not applicable	Not applicable	Not applicable
Hole spacing	Greater than or equal to 8 mm	8 mm	Not applicable	Not applicable	Not applicable	Not applicable
Number of Holes	Min: 4 Max: Dependent on length & hole spacing	Min: 4 Max: 27	Not applicable	Not applicable	Not applicable	Not applicable
Screw Diameter	2.0 mm - 3.2 mm	2.0 mm - 3.2 mm	1.5 mm	1.5 mm - 2 .3 mm	1.0 mm - 2.0 mm	2.3 mm - 3.2 mm
Screw Length	5 mm - 22 mm	8 mm - 22 mm	3.5 mm - 15 mm	4 mm - 19 mm	2 mm - 7 mm	7 mm - 17 mm
Screw Style	maxDrive & crossDrive (Drill-Free, locking [ThreadLock Taper Screw -TLTS], standard)	Drill-Free, locking (ThreadLock Taper Screw -TLTS)	standard, Drill-Free	crossDrive (slotted, standard, low profile) Centre-Drive (standard)	Centre-Drive, Drill-Free (standard)	maxDrive, Drill-Free screw (locking, standard)

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Performance Testing – Non-clinical

Bench testing was used to demonstrate that any differences between the subject and predicate devices do not raise any new safety and effectiveness questions. Mechanical testing was conducted in accordance with ASTM F382 to compare the bending properties of the additive manufactured subject plates against the previously cleared subtractive manufactured predicate plates. The bending resistance and fatigue life of the subject devices was determined to be equivalent or better than the predicate devices.

Steam sterilization validation was performed 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.

Biocompatibility endpoints were evaluated in accordance with ISO 10993. The battery of cytotoxicity, chemical analysis, sensitization and irritation, and chemical/material characterization testing conducted on the subject device were within the pre-defined acceptance criteria, and therefore, adequately addresses biocompatibility for implants with a permanent duration of contact.

Performance Testing – Clinical

Clinical testing was not necessary for the substantial equivalence determination.

Substantial Equivalence Conclusion:

The proposed device has the same intended used as the predicate devices. The performance testing included in the submission demonstrates that the differences in technological characteristics do not raise any new safety and effectiveness questions. The information submitted supports substantial equivalence.