KLS-Martin L.P.
Jennifer Register
Director Regulatory Affairs
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

August 13, 2018

Re: K180962
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: June 16, 2018
Received: June 13, 2018

Dear Jennifer Register:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K180962

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)

**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.***

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*"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."*

# 510(k) Summary K180962

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) summary for KLS Martin Individual Patient Solutions is provided below.

| | |
|---|---|
| ***Date Summary Prepared*** | August 10, 2018 |
| ***Submitter*** | KLS-Martin L.P.<br>11201 Saint Johns Industrial Pkwy S<br>Jacksonville, FL 32246<br>Phone 800-625-1557<br>Fax 904-641-7378 |
| ***510(k) Contact*** | Secure BioMed Evaluations<br>Jennifer Register<br>7828 Hickory Flat Highway<br>Suite 120<br>Woodstock, GA 30188<br>770-837-2681<br>jregister@SecureBME.com |
| ***Trade Name*** | KLS Martin Individual Patient Solutions |
| ***Common Name*** | Plates, Bones |
| ***Code –Classification*** | JEY<br>21 CFR 872.4760. : Class II |
| ***Primary Predicate*** | K163579 KLS Martin Individual Patient Solutions |
| ***Other Predicates*** | K032442 KLS Martin Mandibular Reconstruction System II |
| ***Device Description*** | KLS Martin Individual Patient Solutions is comprised of patient-specific models, metallic fibula and mandible surgical guides, and metallic bone plates. Metallic bone plates are 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.<br><br>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 (ASFM F67) or Ti-6Al-4V (ASTM F136) materials. These patient-specific devices are fixated with previously cleared KLS Martin screws.<br>KLS Martin Individual Patient Solutions consists of the following components:<br>• Plates<br>• Skull Model |

| | |
|---|---|
| | • Screws<br>KLS Martin Individual Patient Solutions consists of the following accessories:<br>• Instrumentation<br>• Metallic fibula and mandible surgical guides |
| ***Intended 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*** | The purpose of this submission is to add optional metallic fibula and mandible surgical guide accessories to be used by the surgeon in bone graft harvesting and resection procedures.<br><br>KLS Martin Individual Patient Solutions is similar to the predicate devices in that it:<br>• has the same indications for use<br>• does not have any labeling changes that affect the intended use of the device<br>• does not alter the fundamental scientific technology<br>• relies on the same materials, fabrication technology and operating principles<br><br>Based on the comparisons described above to the predicate devices and the comparison table below, KLS Martin Individual Patient Solutions does not raise any new issues of safety and effectiveness. |
| ***Non-Clinical Performance Testing Conclusion*** | Non-clinical performance data was performed and submitted with the KLS Martin Individual Patient Solutions Traditional 510(k) (K163579). KLS Martin Individual Patient Solutions is manufactured in accordance with the requirements of the current Good Manufacturing Practices for Medical Devices and follows 21 CFR Subpart C "Design Controls." All verification and validation activities identified by the risk analysis were performed to demonstrate continued conformance with applicable conformance standards which included:<br>• ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity<br>• ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process<br>• ISO 17665-1 Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices<br>• ISO 17665-2 Sterilization of health care products – Moist heat – Part 2: Guidance on the application of ISO 17665-1 |
| ***Substantial Equivalence Summary (Conclusion)*** | The proposed device has the same intended use as the predicate device. The performance testing included in the submission demonstrates that the differences in technological characteristics do not raise new questions of safety or effectiveness. The information submitted supports substantial equivalence. |

TRADITIONAL 510(k): KLS Martin Individual Patient Solutions
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 | | | |
|---|---|---|---|
| | **Individual Patient Solutions**<br><br>**(Subject Device)** | **KLS Martin Individual Patient Solutions K163579**<br><br>**(Primary Predicate)** | **KLS Martin Mandibular Reconstruction System II K032442**<br>**(Predicate)** |
| **Indications for Use** | KLS Martin Individual Patient Solutions implant devices are intended for us in the stabilization and fixation of mandibular fractures and mandibular reconstruction. | 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 us in the stabilization and fixation of mandibular fractures and mandibular reconstruction. |
| **Patient-specific configuration?** | Yes. Devices are manufactured patient-specific, based on a CT scan of the patient. | 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. |
| **Classification** | 21 CFR 872.4760, Class II | 21 CFR 872.4760, Class II | 21 CFR 872.4760, Class II |
| **Product Code** | JEY | JEY | MQN |
| **Material** | CP Titanium or Ti-6A1-4V | CP Titanium or Ti-6A1-4V | CP Titanium or Ti-6A1-4V |
| **Manufacturing Method** | Traditional (Subtractive) 3D (Additive) | Traditional (Subtractive) 3D (Additive) | Traditional (Subtractive) |
| **Sterilization** | Non-sterile (Steam) | Non-sterile (Steam) | Non-sterile (Steam) |
| **Anatomical Sites** | Mandible | Mandible | Mandible |