



Food and Drug Administration
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December 1, 2016

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

Re: K161470
Trade/Device Name: Internal Distraction - Sterile
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: MQN
Dated: May 25, 2016
Received: May 27, 2016

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,


Michael J. Ryan -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

Indications for Use

510(k) Number (if known)

K161470/S002

Device Name

Internal Distraction - Sterile

Indications for Use (Describe)

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, symphysis) and mid-face bones that require gradual distraction.

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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5. 510(K) SUMMARY

Submitter: KLS Martin LP
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Contact Person: Jennifer Damato
Director of Quality MGT and Regulatory Affairs
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Date Prepared: November 18, 2016

Trade Name: Internal Distraction – Sterile

Common Name: Bone plate

Classification Name: External Mandibular Fixator And/or Distractor
Class II, 21 CFR 872.4760, Product Code MQN

Predicate Devices: Zurich Distraction System (K010139) **(Primary Predicate)**
KLS Martin Intraoral Distractor (K973275)
KLS Intra-oral Vertical Distractor (K983515)
KLS Martin Intraoral Zurich Ramus Distractor (K983809)
K-L-W Intraoral Distractor (K991875)
Zurich Pediatric Maxillary Distractor (K000580)
Track 1.0 & 1.5 mm Systems – Tissue Regeneration by
Alveolar Callus Distraction (K002152)
Molina Orbital Malar Distractor (K003883)

Device Description

Internal Distraction - Sterile consists of sterile internal distraction devices intended for the correction of the mandible and mid-face bones that are comprised of several different designs and components intended for bone stabilization and elongation through distraction osteogenesis. It is composed of multiple sizes and shapes of distractor footplates and either fixed or detachable activator arms. The devices are positioned internally with a connected activation arm extending through the soft tissue for external activation. Some devices, due to their anatomical positioning, are directly activated using a patient activation driver, eliminating the need for attaching an activation arm to the device. The distractor footplates are fixated to the bone on either side of the osteotomy using previously cleared bone screws (K943347, K944561, K944565, K971297, K060177). Distraction is achieved by rotating the distractor threaded drive screws with the patient driver, often with an activation arm, which causes a separation of the distractor footplates and induces the body to grow bone and expand soft tissue as a response. Various lengths of distractor drive screws are available to achieve the desired distraction length. Upon completion of

distraction and consolidation of the bone, the screws are removed from the footplates and the distractor is explanted.

The purpose of this bundled submission is to offer the previously cleared KLS Martin LP non-sterile predicate devices intended for mandible and mid-face bones sterile via gamma irradiation and encompasses the following devices:

Zurich Distraction System - K010139: 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.

KLS Intraoral Distractor - K973275: The KLS Martin Intraoral Distractor is intended to be used in the mandible for conditions such as mandibular deficiency or post-traumatic effects of the mandible, where gradual bone distraction is required. (Micrognathia, Hemifacial Microsomia, Congenital Craniofacial Syndromes).

KLS Intra-oral Vertical Distractor - K983515: The KLS Martin Intra-oral Distractor is intended to be used in the conditions of mandibular deficiency or post-traumatic effects of the mandible.

KLS Martin Intraoral Zurich Ramus Distractor - K983809: A uni-directional intraoral device for the distraction of the ascending ramus and mandibular body.

K-L-W Intraoral Distractor - K991875: The indications for use are a uni-directional, intra-oral device for the distraction of facial bones.

Zurich Pediatric Maxillary Distractor - K000580: The Zurich Pediatric Maxillary Distractor is intended for use in the maxilla as a bone stabilizer and lengthening device when correction of congenital mid facial deficiencies or posttraumatic defects require gradual bone distraction.

TRACK Distractors - K002152: The KLS Martin TRACK distractors are intended for use in patients who have totally or partially edentulous mandible or maxilla or small craniofacial bone deficiencies and need an increase in bone height and mass by means of distraction osteogenesis. These patients include those who have traumatic defects, periodontal disease or birth abnormality. The TRACK distractors are designed to provide temporary stabilization and gradual expansion across an osteotomy in the mandibular bone or maxillary bone and thereby increasing the height of the adjacent Alveolar ridge. This device is intended to be removed after consolidation of the callus and prior to final prosthetic reconstruction. The mechanism to achieve distraction is a threaded titanium rod with attached titanium plates, which are fixed to the mandible, or maxilla with titanium bone screws.

Molina Orbital Malar Distractor - K003883: The KLS Martin Molina Orbital Malar Distractor is intended for use in the treatment of cranial and midface conditions such as syndromic craniosynostosis and congenital midface deficiencies in which osteotomies and

gradual bone distraction are indicated. This device is intended to provide temporary stabilization and gradual lengthening of the cranial and midface bones.

Indications for Use

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, symphysis) and mid-face bones that require gradual distraction.

Technological Characteristics/Substantial Equivalence Discussion

Similarities to Predicate Devices

Internal Distraction - Sterile is very similar to the predicate devices with respect to intended use, but identical in materials, manufacturing process, principles of operation, design mechanisms, and performance. Placement and fixation of the Internal Distraction - Sterile devices is identical to the methods used for the predicate devices.

Differences to Predicate Devices

Internal Distraction – Sterile differs from the predicate devices in that it will be provided in sterile packaging and will have different stock numbers from the originally cleared stock numbers to identify the product as sterile. In addition, the intended use differs slightly in that Internal Distraction – Sterile will be intended for correction of bones in the mandible and mid-face only, and will not include cranial bones.

Non-Clinical Performance Data

Biocompatibility Testing

Biocompatibility requirements were assessed in accordance with FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO 10993, ‘Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,’” as recognized by FDA. The patient-contacting materials Titanium Alloy (Ti-6Al-4V) and CP Titanium used for the Internal Distraction – Sterile devices and their components were tested for biocompatibility and are previously cleared in all predicate devices. The Internal Distraction – Sterile devices and their components are comprised of the same materials, have the same chemical composition, undergo the same manufacturing processes, and have the same body contact duration as these devices; therefore, biocompatibility testing for Internal Distraction – Sterile is not needed.

Endotoxin Testing

Bacterial Endotoxins testing was conducted in accordance to ANSI/AAMI ST72:2011, USP <85>, and EP 2.6.14 for detection and quantitation of bacterial endotoxins. The results of the testing demonstrate that the subject devices conform to the required endotoxin units per device for medical devices and meet pyrogen limit specifications.

Performance Testing – Bench

Axial load testing, bending torsion testing, axial-torsion testing, and transverse shear testing were performed to evaluate the mechanical properties of the subject devices. All devices passed design requirements for material properties, manufacturing tolerances, axial resistance, and torsional loading. The results of the testing demonstrate the devices are sufficiently capable of withstanding the anatomical loads placed upon them and allow for effective and safe boney movement during their intended use.

Clinical Performance Data

Clinical testing was not necessary for the determination of substantial equivalence.

Conclusion

Internal Distraction - Sterile is very similar in its intended use, is identical in design, function, manufacturing process, and is composed of the same materials as the predicate devices. The similarities and differences in technological characteristics do not raise new questions of safety or effectiveness. Internal Distraction – Sterile will encompass all the previously cleared predicate devices intended for correction of mandible and mid-face bones and provide them sterile. Therefore, the information presented supports substantial equivalence of Internal Distraction – Sterile to the predicate devices.