DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 5, 2017

KLS Martin LP
Jennifer Damato
Director of Quality MGT & Regulatory Affairs
11201 Saint Johns Industrial Parkway South
Jacksonville, Florida 32246

Re: K163315
Trade/Device Name: Internal Distraction - Sterile
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: PBJ
Dated: April 3, 2017
Received: April 4, 2017

Dear Ms. Damato:

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. Hoffmann -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine 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)*
K163315

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 cranial 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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5. 510(K) SUMMARY

Submitter:	KLS Martin LP 11201 Saint Johns Industrial Pkwy S Jacksonville, FL 32246
Contact Person:	Jennifer Damato Director of Quality MGT and Regulatory Affairs Phone: 1-800-625-1557 Fax: 904-641-7378
Date Prepared:	May 4, 2017
Trade Name:	Internal Distraction – Sterile
Common Name:	Preformed nonalterable cranioplasty plate
Classification Name:	Cranial Distraction System Class II, 21 CFR 882.5330, Product Code PBJ
Predicate Devices:	Zurich Distraction System (K010139) (**Primary)**

Device Description

Internal Distraction - Sterile consists of sterile internal distraction devices intended for the correction of cranial 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.

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The purpose of this submission is to offer the previously cleared KLS Martin LP non-sterile predicate cranial distractors sterile via gamma irradiation and encompasses the following device:

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.

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 cranial bones that require gradual distraction.

Technological Characteristics/Substantial Equivalence Discussion

Similarities to Predicate Devices

Internal Distraction - Sterile is similar to the Zurich Distraction System (K010139) predicate device with respect to intended use, but identical in materials, manufacturing process, principles of operation, and placement/fixation methods. The design mechanisms are similar with regard to the drive screws, distractor body, footplate shapes and sizes, distractor drive lengths, activators, and screws used to attach the footplates to the bone. The subject device performance characteristics are the same and testing performed demonstrates the devices are safe and effective for the intended use.

Differences to Predicate Devices

Internal Distraction – Sterile differs from the Zurich Distraction System (K010139) predicate device 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 only from the predicate device in that Internal Distraction – Sterile will be intended for correction of bones in the cranium, and will not include mid-face or mandible bones. The design mechanisms differ slightly in the subject devices compared to the predicate devices in that the distractors are manufactured with a ratcheting mechanism and specific activation arms are designed to be detachable based on patient need and distraction location.

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

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tested for biocompatibility and are previously cleared in the predicate device. 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.

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