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

August 27, 2015

KLS-Martin L.P.
Mr. Gary Moore
Quality MGT and Regulatory Affairs Manager
11201 Saint Johns Industrial Parkway South
Jacksonville, Florida 32246

Re: K150771
Trade/Device Name: RxG Distraction System
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: PBJ
Dated: July 21, 2015
Received: July 24, 2015

Dear Mr. 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 yours,

Carlos L. Pena -S

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)*
K150771

Device Name
RxG Distraction System

Indications for Use *(Describe)*
The RxG Distraction System includes devices intended for use in bone stabilization and elongation (lengthening) in the correction of congenital or developmental defects in cranial reconstruction for the pediatric and adult populations.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

KLS martin L.P.
P.O. Box 16369 • Jacksonville, FL 32245-6369
904-641-7746 or 800-625-1557 • Fax 904-641-7378
www.klsmartinnorthamerica.com

510(k) Summary

21 CFR 807.92

Submitter:	KLS-MARTIN L.P. 11201 Saint Johns Industrial Pkwy S Jacksonville, FL 32246
Contact Person:	Jennifer Damato Director of Quality MGT & Regulatory Affairs Phone: 800-625-1557 Fax: 904-641-7378
Date Prepared:	August 19, 2015
Trade Name:	RxG Distraction System
Common Name:	Cranial Distraction System
Classification:	Preformed nonalterable cranioplasty plate Class II, 21 CFR 882.5330, Product Code PBJ
Primary Predicate:	LactoSorb Distraction **(K002083)**
Reference Devices:	RxG Distraction System **(K133304)** Resorb-X G **(K121606)**

Device Description:

The RxG Distraction System consists of implantable devices used to lengthen or increase the dimension of cranial bones through distraction osteogenesis. It is composed of multiple sizes and shapes of RxG footplates and a threaded drive screw connected to an activation arm. The device is positioned internally with the connected activation arm extending through the soft tissue for external activation. The RxG footplates are secured to the bone on either side of the osteotomy with SonicPins RxG. Distraction is achieved by turning the activation arm with the patient activation driver, causing the plates to separate. Various lengths of drive screws are available to achieve up to 40 mm of distraction. Upon completion of distraction and consolidation of the bone, the drive screw is detached from the RxG footplates and removed, while the RxG footplates and SonicPins RxG remain implanted and are resorbed in 12-14 months.

The purpose of this Traditional 510(k) is to expand the indications for use of the RxG Distraction System to include cranial use in the pediatric and adult populations.

Indications for Use:

The RxG Distraction System includes devices intended for use in bone stabilization and elongation (lengthening) in the correction of congenital or developmental defects in cranial reconstruction for the pediatric and adult populations.

KLS martin L.P.
P.O. Box 16369 • Jacksonville, FL 32245-6369
904-641-7746 or 800-625-1557 • Fax 904-641-7378
www.klsmartinnorthamerica.com

Technological Characteristics / Substantial Equivalence:

	RxG Distraction System (Subject Device)	LactoSorb Distraction (Primary Predicate – K002083)	RxG Distraction System (Reference Device – K133304)	Resorb-X G (Reference Device – K121606)
Indications for Use	The RxG Distraction System includes devices intended for use in bone stabilization and elongation (lengthening) in the correction of congenital or developmental defects in cranial reconstruction for the pediatric and adult populations.	The Lorenz Resorbable Distraction System includes devices intended for use in bone stabilization and elongation (lengthening) when correction of oral (alveolar ridge), cranial, maxillofacial deficiencies or post-traumatic defects require gradual bone distraction. The Lorenz Resorbable Distraction System also includes devices intended for use in bone stabilization and elongation (lengthening) when correction of mandibular deficiencies or post-traumatic defects require gradual bone distraction patients two (2) years old or younger. The mid-face distractor is intended primarily for LeFort III osteotomies.	The RxG Distraction System includes devices intended for use in bone stabilization and elongation (lengthening) in the correction of congenital or developmental defects of the midface and alveolar ridge. The RxG Distraction System also includes devices intended for use in bone stabilization and elongation (lengthening) in the correction of congenital or developmental defects of the mandible in patients 2 years old or younger. The RxG Distraction System is not intended for load-bearing applications in adult or adolescent populations.	Resorb-X G is intended for use in non-load bearing fracture repair and reconstructive procedures in adolescent and adult populations. In addition, resorbable meshes, plates and pins may be used in non-loading bearing applications for maintaining the relative position of, and/or containing, bony fragments, bone grafts (autograft or allograft), or bone graft substitutes in cranial reconstruction.
Contraindications	1. Active infection 2. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation. 3. Patients with limited blood supply, insufficient quantity or quality of bone, or latent infection. 4. Patients or parents/guardians of patients are unwilling or incapable of following postoperative care instructions. 5. Patients with bleeding disorders or poor wound healing. 6. Patients with metabolic disorders.	1. Active infection 2. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation. 3. Patients with limited blood supply, insufficient quantity or quality of bone, or latent infection. 4. Patients, or parents/guardians of patients are unwilling or incapable of following postoperative care instructions. 5. Patients with bleeding disorders or poor wound healing. 6. Patients with metabolic disorders.	1. Active infection 2. Foreign body sensitivity	1. High-load regions in the absence of traditional rigid fixation 2. Active or latent infections 3. Patients in a bad general state of health or suffering from metabolic disorders
Target Population	Pediatrics and Adults	Pediatrics and Adults	Pediatrics and Adults	Pediatrics and Adults
Anatomical Sites	Cranial	Cranial, Oral, Mandibular, and Maxillofacial	Oral, Mandibular, and Maxillofacial	Cranial

KLS martin L.P.
P.O. Box 16369 • Jacksonville, FL 32245-6369
904-641-7746 or 800-625-1557 • Fax 904-641-7378
www.klsmartinnorthamerica.com

Technological Characteristics / Substantial Equivalence, Continued:

	RxG Distraction System (Subject Device)	LactoSorb Distraction (Primary Predicate – K002083)	RxG Distraction System (Reference Device– K133304)	Resorb-X G (Reference Device – K121606)
Materials				
Bone Plates	85:15 PLLA-PGA	82:18 PLLA-PGA	85:15 PLLA-PGA	85:15 PLLA-PGA
Bone Pins/Screws	85:15 PLLA-PGA	82:18 PLLA-PGA	85:15 PLLA-PGA	85:15 PLLA-PGA
Drive Screw	TI-6AL-4V or Stainless Steel	Stainless Steel	TI-6AL-4V or Stainless Steel	N/A
Activation Arm	TI-6AL-4V or Stainless Steel	TI-6AL-4V , Stainless Steel	TI-6AL-4V or Stainless Steel	N/A
Sterility	Provided Sterile (Gamma Radiation)	Provided Sterile (ETO)	Provided Sterile (Gamma Radiation)	Provided Sterile (Gamma Radiation)
Standards Met	See Section 9.0	ASTM F136, ASTM F138	Same as current submission	ISO 10993-1, -5, -12, -18 ISO 11137-1, -2, 11737-1, -2
Where used (hospital, home, ambulance, etc)	Health Care Facilities/ Hospitals	Health Care Facilities/ Hospitals	Health Care Facilities/ Hospitals	Health Care Facilities/ Hospitals
Breakdown Products (Plates, Pins/Screws)	H_2O and CO_2	H_2O and CO_2	H_2O and CO_2	H_2O and CO_2
Resorption Time	12 - 14 months	12 months	12 - 14 months	12 - 14 months
Max. Distraction Distance				
Cranial Distractor	40 mm	40 mm	N/A	N/A
Alveolar Ridge Distractor	N/A	25 mm	25 mm	N/A
Midface Distractor	N/A	40 mm	30 mm	N/A
Mandibular Distractor	N/A	25 mm	30 mm	N/A
Plate Thickness	2 - 5 mm	2 - 5 mm	2 - 5 mm	0.3 - 1.0 mm
Cumulative Max. Plate Volume	7840 mm^3	Unknown	7840 mm^3	15876 mm^3
Pin/Screw Diameter	1.6 mm or 2.1 mm	1.5 – 2.5 mm	2.1 mm	1.6 mm or 2.1 mm
Pin/Screw Length	3 - 9 mm	6 - 9 mm	3 - 7 mm	3 - 7 mm

KLS martin L.P.
P.O. Box 16369 • Jacksonville, FL 32245-6369
904-641-7746 or 800-625-1557 • Fax 904-641-7378
www.klsmartinnorthamerica.com

Nonclinical Testing:
Nonclinical testing to support substantial equivalence of the RxG Distraction System is summarized in the following table:

Test	Summary	Results
Performance Bench	Comparative mechanical testing was performed between the RxG distractor and LactoSorb distractor to measure deformation and distraction distance. Acceptance Criteria: The RxG distractor should exhibit less deformation than the LactoSorb distractor. Devices were affixed to sawbone blocks to simulate an osteotomy, and then placed in a waterbath of Ringer's solution for the duration of testing. After the 48 hour latency period, distraction and consolidation were simulated over a period of 52 days. Deformation measurements were taken at regular intervals.	Final deformation was determined by measuring the distance between the two footplates of each distractor. The RxG Distraction System exhibited less deformation and achieved greater distraction distance than the LactoSorb distractor. The results of the testing showed substantial equivalence to the primary predicate.
Biocompatibility	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 battery of testing included the following tests: • Toxicology • Cytotoxicity • Chemical Analysis	The RxG Distraction System patient-contacting materials Resorb xG, Ti-6Al-4V, and Stainless Steel used for the components in the subject device are previously cleared in K133304, have the same chemical composition, undergo the same manufacturing processes, have the same body contact, and are subjected to the same sterilization methods as the reference device. The results of the testing showed that the biocompatibility requirements have been met. No claim of "pyrogen free" is made.
Sterility	Bioburden, dose verification, and tests of sterility for the gamma sterilization process were validated in accordance with ISO 11137-1, -2, as well as ISO 11737-1, -2 to achieve an SAL of 10^{-6}.	The subject device undergoes the same sterilization methods as the reference devices in K121606 and K133304. The results of the testing showed that the sterilization doses achieve an SAL of 10^{-6} for the devices.
Packaging & Shelf-Life	Validation of package integrity was performed in accordance with ISO 11607-1, -2. Real-time stability testing was performed for the Resorb xG implants in K121606.	The packaging & shelf-life for the subject device is identical to the reference device in K133304. The results of the testing showed that the packaging is suitable for the intended sterilization process and can maintain sterility during the intended shelf-life period of 5 years.

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

Conclusions:
The RxG Distraction System has the same intended use as the primary predicate, the LactoSorb Distractor (K002083). In addition, the subject device has the same technological characteristics as the RxG Distraction System (K133304) and Resorb-X G (K121606) reference devices. The nonclinical testing results and similarities in technological characteristics do not raise new issues of safety or effectiveness and demonstrate substantial equivalence to the predicate devices.