November 21, 2023

KLS-Martin L.P.
Daphne Vincent
Regulatory Affairs Project Manager
11201 Saint Johns Industrial Parkway S
Jacksonville, Florida 32246

Re: K230211
Trade/Device Name: CranioXpand
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: PBJ
Dated: October 24, 2023
Received: October 24, 2023

Dear Daphne Vincent:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Adam D. Pierce -S

Digitally signed by Adam D. Pierce -S
Date: 2023.11.21 14:31:43 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230211

Device Name
CranioXpand

Indications for Use *(Describe)*
The KLS Martin CranioXpand Spring system is indicated for use in the treatment of cranial conditions such as craniosynostosis and congenital deficiencies in which osteotomies and gradual bone distraction are indicated for the infant pediatric subpopulation (29 days to < 2 years of age). The CranioXpand implants are implantable single-use products intended for temporary stabilization and distraction of the bony cranial roof during and after surgery. This device is intended to be removed after bone consolidation.

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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510(k) Summary

Submitter:	KLS-Martin L.P. 11201 Saint Johns Industrial Pkwy S. Jacksonville, FL 32246
Primary Contact:	Daphne Vincent Regulatory Affairs Project Manager Phone: 800-625-1557 Email: daphne.vincent@klsmartin.com
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Date Prepared:	November 21, 2023

Trade Name:	CranioXpand
Classification Name:	Cranial Distraction System
Regulation Description:	Preformed non-alterable cranioplasty plate
Regulation Numbers:	882.5330
Product Code:	PBJ

Predicate Device:	OsteoMed SmartFlex Cranial Spring Distraction System [K123885]
Classification Name:	Cranial Distraction System
Regulation Description:	Preformed non-alterable cranioplasty plate
Regulation Numbers:	882.5330
Product Code:	PBJ

Device Description Summary:

The KLS Martin CranioXpand Spring System consists of implantable spring distractors and supporting instruments intended for temporary stabilization and distraction of the bony cranial roof during and after surgery through distraction osteogenesis. The CranioXpand Springs are offered in various sizes. The spring features include rounded atraumatic contours to ensure optimal embedding in soft tissue with curved ends to ensure the devices can

securely anchor in the bone. Two springs are provided as part of the CranioXpand system for anterior and posterior placement on the osteotomies. The springs are removed after adequate bone formation or after the bone consolidation phase is complete. These devices are typically left in the implanted location for 3 - 6 months before explantation.
The CranioXpand Instruments are accessories used to facilitate spring size selection, and spring insertion and positioning.

The CranioXpand device is offered in the following models:

Model Number	Device Size	Device Information
25-025-10-71	CranioXpand Spring (1.0 mm)	1.0 mm Wire Thickness; No Marking on Spring
25-025-12-71	CranioXpand Spring (1.2 mm)	1.2 mm wire thickness; Two rings laser marked on spring
25-025-16-71	CranioXpand Spring (1.6mm)	1.6 mm wire thickness; Six rings laser marked on spring

The different models of the CranioXpand device are the same except for difference in wire thickness and the marking on the spring indicating wire thickness.

This submission includes the following accessories:

Model Number	Accessory Name	Intended Use
25-025-52-07	Spring Selection Instrument	Used to facilitate spring size selection
25-025-42-07	Forward Opening Insertion Instrument	Used to aid with implantation and positioning of anterior spring
25-25-43-07	Backward Opening Insertion Instrument	Used to aid with implantation and positioning of posterior spring

Indications for Use:

The KLS Martin CranioXpand Spring system is indicated for use in the treatment of cranial conditions such as craniosynostosis and congenital deficiencies in which osteotomies and gradual bone distraction are indicated for the infant pediatric subpopulation (29 days to < 2 years of age). The CranioXpand implants are implantable single-use products intended for temporary stabilization and distraction of the bony cranial roof during and after surgery. This device is intended to be removed after bone consolidation.

Indications for Use Comparison:

The intended use and indications of use of the subject device and the predicate device are the same. Both devices are indicated for use in the treatment of cranial conditions such as syndromic craniosynostosis and congenital deficiencies in which osteotomies and gradual bone distraction are indicated. Both devices are intended to provide temporary stabilization and gradual lengthening in the cranium and are intended to be removed after consolidation.

The only minute difference is that the predicate device is meant for use in cranial bones, whereas the subject device is meant for use in the bony cranial roof. This is not a cause for concern as the area indicated by the subject device is a subset of the area indicated by the predicate device.

Technological Comparison

The subject and the predicate devices share similar technological characteristics. The similarities and differences are detailed below. Any differences in technological features between the subject and predicate devices do not raise new or different questions of safety and effectiveness.

- *Similarities to Predicate Device*:
  The technological characteristics and operational principle for the subject device and predicate device are the same. In both, the technological characteristics of a spring distractor is utilized to achieve the operational principle of distraction osteogenesis. The design of both devices is similar. Both devices have a design utilizing a spring mechanism anchored by feet and are accompanied by instruments aiding with spring implantation and spring removal. The material, the target population, and sterilization method for both devices are the same. Both are manufactured using implant grade stainless steel (316 LVM (1.4441) according to ASTM F138). The target population for both is the infant pediatric subpopulation. The sterilization method for both springs is gamma sterilization whereas the instruments are offered non-sterile.

- *Differences from Predicate Device*:
  Although both devices have similar designs, there are slight differences. The subject device consists of a V shaped springs with a center helix whereas the predicate device consists of a U shaped design with no center helix. The predicate device variants are distinguished by force, while the subject device variants are distinguished by diameter. The differences in the springs of the subject and predicate devices are addressed with performance data.

Specification/ Characterization	CranioXpand [K230211]	OsteoMed SmartFlex Cranial Spring Distraction System [K123885]	Comment
Indications for Use	The KLS Martin CranioXpand Spring system is indicated for use in the treatment of cranial conditions such as craniosynostosis and congenital deficiencies in which osteotomies and gradual bone distraction are indicated for the infant pediatric subpopulation (29 days to < 2 years of age). The CranioXpand implants are implantable single-use products intended for temporary stabilization and distraction of the bony cranial roof during and after surgery. This device is intended to be removed after bone consolidation.	The OsteoMed SmartFlex Cranial Spring Distraction System is intended for use in the treatment of cranial conditions such as syndromic craniosynostosis and congenital deficiencies in which osteotomies and gradual bone distraction are indicated. This device is intended to provide temporary stabilization and gradual lengthening of the cranial bones. This device is intended to be removed after consolidation. The OsteoMed SmartFlex cranial spring distraction system is intended for single patient use only. Target population: pediatrics; sub-population - infant greater than 1 month to 2 years of age	Similar
Intended Population	Infant	Infant	Same
Anatomical Site	Cranium	Cranium	Same
Function	Distraction of cranial bones	Distraction of cranial bones	Same
Technological Characteristics	Spring Distractor	Spring Distractor	Same
Design	Distraction via spring forces and anchored by hooks of feet	Distraction via spring forces and anchored by hooks of feet	Same
Configuration	V shaped springs with a center helix	U shaped design with no center helix	Different
Device Material	Stainless Steel (316 LVM (1.4441) according to ASTM F-138)	Stainless Steel (316 SS LVM according to ASTM F-138)	Similar
Sterility	Provided Sterile (Gamma Radiation)	Provided Sterile (Gamma Radiation)	Same

Summary of Non-Clinical Performance Testing

Biocompatibility Testing:

The CranioXpand device is categorized as a long term implant in contact with tissue/bone (>30 days) in accordance with Attachment A of the FDA biocompatibility guidance and was evaluated for the following biocompatibility endpoints: cytotoxicity, sensitization, irritation or intracutaneous reactivity, material mediated pyrogenicity, genotoxicity, carcinogenicity, implantation, acute systemic toxicity, and subacute, subchronic and chronic toxicity.

The Spring Selection Instrument, Insertion Instrument Forward Opening and Insertion Instrument Backward Opening accessories are categorized as external communicating devices with limited contact (≤ 24 h) in accordance with Attachment A of the FDA biocompatibility guidance and were evaluated for the following biocompatibility endpoints: cytotoxicity, sensitization, irritation or intracutaneous reactivity, acute systemic toxicity and material-mediated pyrogenicity.

The CranioXpand device and accessories were evaluated per FDA guidance "*Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management Process*" and found to comply with the requirements of ISO 10993-1:2018 thus are considered biocompatible.

Performance Bench Testing:

The performance of the subject and predicate springs was analyzed via bench testing measuring force elicited during cyclical testing. The acceptance criteria of the test were met, thus demonstrating that the performance of the subject device is substantially equivalent to that of the predicate device. Additionally, performance testing was conducted on the insertion instrument and selection instruments.

The following performance tests were completed for the CranioXpand device and accessories:

Test Name	Method	Conclusion
Spring Testing	A comparison of the performance of the subject and predicate springs via force measurements during cyclical testing was conducted by recording the force while repeating the following cycle 6 times: first compressing the spring (until distance between arms was 10mm), holding the compression (5 seconds), then decompressing the spring.	Pass

Test Name	Method	Conclusion
Insertion Instruments Testing	A visual and holding inspection was performed of whether the instrument could appropriately open, close, and pick up the spring. Measurements were conducted to verify that the instrument could compress the spring legs sufficiently (<17mm).	Pass
Selection Instrument Testing	The force output of the selection instrument via static testing was determined by recording the force while first applying a load on the instrument (1.0mm/s until distance between legs is 15mm), holding the position (5 seconds), then unloading the instrument (same speed). Verification of whether the selection instrument could withstand 1000 load cycles at continuous load via dynamic testing was determined by recording the force while repeating the following steps until 1000 cycles are reached: first applying a load on the instrument (45mm at test speed of 0.5mm/s), holding the position, (1 second) then unloading the instrument (same speed).	Pass

Conclusion

CranioXpand has the same intended use and similar technological characteristics to the predicate device. The differences in technological features between the subject and predicate devices do not raise new or different questions of safety and effectiveness as supported by the performance testing. Therefore, the CranioXpand is substantially equivalent to the predicate device.