November 21, 2023

Chendu MedArt Medical Scientific Co., Ltd.
℅ Joyce Yang
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square,
Nanshan District
Shenzhen, Guangdong 518100
China

Re: K221606
Trade/Device Name: Absorbable Cranial Flap Fixation System
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Cover
Regulatory Class: Class II
Product Code: GXR
Dated: October 20, 2023
Received: October 23, 2023

Dear Joyce Yang:

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 09:27:14 -05'00'

Adam D. Pierce, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221606

Device Name
Absorbable Cranial Flap Fixation System

Indications for Use *(Describe)*
The Absorbable Cranial Flap Fixation System is intended to be used for fixation of cranial bone flaps following craniotomy.

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

Date prepared: November 15, 2023

1. Submitter

Applicant Name	Chengdu MedArt Medical Scientific Co., Ltd.
Address	No.102, Tianying Road, Chengdu High-tech Industrial Development Zone, 611731 Sichuan, China
Contact person	Huaping Ran
Phone	086-28-87958626
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2. Device Identification

Trade Name	Absorbable Cranial Flap Fixation System
Regulation Number	21 CFR § 882.5250
Device Class	II
Regulation Description	Burr hole cover
Product Code	GXR

3. Predicate Device

Trade Name	RapidFlap LS Cranial Fixation Flap System
Submission Number	K130309
Regulation Number	21 CFR § 882.5250
Device Class	II
Regulation Description	Burr hole cover
Product Code	GXR
Manufacturer	Biomet Microfixation

4. Device Description

The Absorbable Cranial Flap Fixation System is comprised of a lower disc, an upper disc, a connecting rod and a rotating lock. The lower disc consists of a circular disk through which the connecting rod is centrally extruded outward. The upper disc consists of a circular disk with a threaded hole to accept the connecting rod. The upper disc is driven to move axially along the connecting rod by rotating the rotating lock so that the discs tightly grip the bone flap and provide rigid attachment and coplanar alignment to the surrounding bone.

The Absorbable Cranial Flap Fixation System is made from poly-L-lactic acid. The device is supplied sterile and is intended for single use.

The Heat/Contouring Pen is an accessory used to cut off the excess connecting rod of the Absorbable Cranial Flap Fixation System. The Heat/Contouring Pen is a disposable, lithium battery powered handheld device that includes a cutting heating head and a smoothing heating head. The Heat/Contouring Pen is supplied sterile and is intended for single use.

5. Indications for Use

The Absorbable Cranial Flap Fixation System is intended to be used for fixation of cranial bone flaps following craniotomy.

6. Tabular Comparison of the Subject Device and Predicate Device

Specification/ Characterization	**Subject Device:** Absorbable Cranial Flap Fixation System (K221606)	**Predicate Device:** RapidFlap LS Cranial Fixation Flap System (K130309)	**Comments**
Indication for Use	The Absorbable Cranial Flap Fixation System is intended to be used for fixation of cranial bone flaps following craniotomy.	The RapidFlap LS Cranial Fixation Flap System is indicated for use in rigid fixation of a craniotomy in adult and pediatric populations.	Similar
Material	Poly-L-lactic acid	Polylactic/polyglycolic acid copolymer	Similar
Material property	Resorbable	Resorbable	Same
Sterilization	Sterile by EO	Sterile by EO	Same

Specification/ Characterization	Subject Device: Absorbable Cranial Flap Fixation System (K221606)	Predicate Device: RapidFlap LS Cranial Fixation Flap System (K130309)	Comments
Component description	Lower disc and upper disc (each consisting of a circular disk with a threaded hole) connected by a connecting rod	Inner and outer plates (each consisting of a circular disk with a threaded hole) connected by a threaded central post	Similar
Accessories	Battery operated Heat/Contouring Pen with cutting heating head and smoothing heating head	LactoSorb SE Heat Pen with cutting tip and contouring tip	Different

7. Summary of Non-clinical Testing

The Absorbable Cranial Flap Fixation System is made from poly-L-lactic acid.

The main performance of the product is tripping force, compression force and torque force and the test results showed no statistical difference between the subject device and predicate device.

Test	Test method summary	Results
Tripping Force	The purpose of this test is to determine the locking function of the device is comparable to the predicate device. 1) The devices were fastened with the fixture of the tensile testing machine. 2) Apply tension at the stretching speed of 20 mm/min until the upper disc is released and record the tension force 3) Compared the test result of the subject and predicate device.	Pass No statistical difference between the predicate and subject device.
Compression Force	1) Place the upper/lower disk on the flat test bench. 2) Apply pressure to the disk with the microcomputer control electronic universal tester and record the maximum force required for the device to deform or crack. Compare the	Pass The acceptance criteria were met, and the results showed no statistical difference

Test	Test method summary	Results
	results with the predicate and ensure that the acceptance criteria is met.	between the subject and predicate device.
Torque Force	Clamp and fix both end of the connecting rod and rotate the connecting plate at a fixed rotational speed until the connecting rod is damaged or stops rotating and record the maximum force required for the connecting rod to break.	Pass No statistical difference between the subject and predicate device.

The biocompatibility evaluation for the Absorbable Cranial Flap Fixation System was conducted in accordance with the FDA guidance document "*Use of International Standard ISO 10993-1 "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process"".*

Test	Results	Conclusion
In Vitro Cytotoxicity Test (ISO 10993-5:2009)	The percent cell viability of the subject device was 94.7% (＞70%).	Pass Non - Cytotoxic
Skin Sensitization Test (ISO 10993-10:2010)	Under the conditions of the study no visible change was observed in the test article groups.	Pass Non - Sensitizer
Intracutaneous Reactivity Test (ISO 10993-10:2010)	Under the conditions of the study the overall mean score difference between the test article and vehicle was 0.56, less than 1.0.	Pass Non - Irritant
Acute Systemic Test (ISO 10993-11:2017)	Under the conditions of the study the no toxic response was observed in the sample group.	Pass Not Systemically Toxic
Material-Mediated Pyrogenicity (ISO 10993-11:2017)	The results showed that the body temperature of the three rabbits did not increase more than 0.5 ℃.	Pass Not Pyrogenic

Test	Results	Conclusion
Bone Implantation Test (ISO 10993-6:2016)	Under the conditions of the study the histopathological response of the test article was similar with the control sample.	Pass
Subchronic Systemic Toxicity (ISO 10993-11:2017)	Under the conditions of the study no toxic response was observed.	Pass No evidence of systemic toxicity
Degradation Test (ISO 10993-13:2010)	Comparable results to the control group for blood lactate concentration, cerebrospinal fluid lactate concentration, pH, and histopathological.	Degradable and no toxicity
Genotoxicity (ISO 10993-3:2014)	- The result of Ames test for the test article was negative. - The results indicated that the test sample could not induce chromosome aberrations. - The results showed that the test article did not induce gene mutation at TK locus.	Pass Non - genotoxic

The LAL endotoxin testing demonstrates that the sterile Absorbable Cranial Flap Fixation System conforms to the required ≤2.15 EU/device.

8. Conclusion

The subject device, Absorbable Cranial Flap Fixation System, has the same intended use, design, function, and is composed of a similar material to the predicate device, RapidFlap LS Cranial Fixation Flap System. Based on the comparison of the technological and functions characteristics, intended use and performance data, the Absorbable Cranial Flap Fixation System is substantially equivalent to the predicate device, RapidFlap LS Cranial Fixation Flap System.