June 3, 2020

Ossaware Biotech Co., Ltd.
Meng Huang
General Manager
No. 51, Xinggong Rd.
Shenkang Hsiang, 50971 Tw

Re: K192310
Trade/Device Name: CirFIX Cranial Bone Fixation System: Flap Fixator and Burr Hole Cover
Regulation Number: 21 CFR 882.5250
Regulation Name: Burr Hole Cover
Regulatory Class: Class II
Product Code: GXR
Dated: May 1, 2020
Received: May 1, 2020

Dear Meng Huang:

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. 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 located 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.

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) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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, Ph.D.
Acting Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192310

Device Name
CirFIX Cranial Bone Fixation System: Flap Fixator and Burr Hole Cover

Indications for Use *(Describe)*
CirFIX Cranial Bone Fixation System: Flap Fixator is intended for use to post-craniotomy bone flap fixation and the Burr Hole Cover is to be used for covering a single burr hole.

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

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of the CirFIX® Cranial bone fixation system Submission.

Date: June 3, 2020

Submitted by	OSSAWARE BIOTECH CO., LTD. No. 51, Xinggong Rd., Shenkang Hsiang, Changhua(50971), Taiwan
Contact Person	Meng Feng Huang General Manager Phone: +886-4-7980819 E-mail: FDA@CUSMED.COM
Trade Name	CirFIX® Cranial bone fixation system: Flap Fixator and Burr Hole Cover
Common Name	Burr hole cover
Proposed Class	Class II
Classification Name and Reference	882.5250 Burr hole cover
Device Product Code, Device Panel	GXR, Neurology
Predicate Device	Legally marketed predicate devices to which substantial equivalence is claimed: ● Cranial Loop, Cranial Loop L And Cranial Loop Xl And Cranial Bone Fixation System_K132044 ● Cranial Cover_K160739

Device Description	The CirFIX® Cranial bone fixation system: Flap Fixator is a biocompatible, postoperative cranial bone fixation system that fixes the bone flap to the skull after craniotomy and Burr Hole Cover which is for covering a single burr hole resulting from cranial surgery. The CirFIX® Cranial bone fixation system is provided in sterile, for a single use. With available sizes for cranial thickness ranging from 3 mm to 14 mm and burr holes with an epicranial diameter from 10 to 15 mm, made by standard perforators or with spherical drills, can be covered.
Intended Use and Indications for Use	The CirFIX® Cranial bone fixation system: Flap Fixator is intended for use to post-craniotomy bone flap fixation and the Burr Hole Cover is to be used for covering a single burr hole.
Summary of the Technological Characteristics	The subject CirFIX® Cranial bone fixation system: Flap Fixator and Burr Hole Cover and the predicates are identical in indications for use, surgical technique and anatomical implantation site. The subject CirFIX® Cranial bone fixation system and the predicates share similar design features: ● Method of fixation like a clamp. ● Comparable size, material.
Summary of Non-Clinical Testing	Mechanical and performance testing confirms the CirFIX® Cranial bone fixation system: Flap Fixator and Burr Hole Cover performs as intended and substantially equivalent to the predicate device.
Conclusion	Based on the design features, the use of established well known materials, feature comparisons, indications for use, and results of the mechanical testing, the CirFIX® Cranial bone fixation system has demonstrated substantial equivalence to the identified predicate devices.

Technological characteristics and comparison to predicate devices

Documentation was provided to demonstrate that the CirFIX® Cranial bone fixation system: Flap Fixator and Burr Hole Cover is substantially equivalent to the legally marketed predicates. The CirFIX® Cranial bone fixation system: Flap Fixator and Burr Hole Cover is substantially equivalent to the predicate devices in indications for use, anatomical implantation site, materials, design features, mechanical performances, and operating principles. Mechanical testing shows the mechanical strength of the Subject device to be equivalent or better than the predicate devices.

A side-by-side comparison of the CirFIX® Cranial bone fixation system: Flap Fixator and Burr Hole Cover to the predicate devices as following:

Device	Gap analysis	CirFIX® Cranial bone fixation system: Flap Fixator and Burr Hole Cover	Cranial Loop, Cranial Loop L And Cranial Loop XI And Cranial Bone Fixation System	Cranial Cover
Company	-	OssAware Biotech Co., Ltd.	Neos Surgery S.L.	Neos Surgery S.L.
510(k) No.	-	K192310	K132044	K160739
Product Code	Same	GXR - burr hole cover	GXR - burr hole cover	GXR - burr hole cover
Device Description	Same	The CirFIX® Cranial bone fixation system: Flap Fixator is a biocompatible, postoperative cranial bone fixation system that fixes the bone flap to the skull after craniotomy and Burr Hole Cover which is for covering a single burr hole resulting from cranial surgery. The CirFIX® Cranial bone fixation system is provided in sterile, for a single use. With available sizes for cranial thickness ranging from 3 mm to 14 mm and burr holes with an epicranial diameter from 10 to 15 mm, made by standard perforators or with spherical drills, can be covered.	The Cranial LOOP Cranial Bone Fixation Systems: Cranial LOOP, Cranial LOOP (L) and Cranial LOOP (XL), are long-term implantable devices indicated for postcraniotomy bone flap fixation. In cranial bone fixation procedures, the Cranial LOOP (FC050000) and Cranial LOOP L (FC50100) are for use with the calvarial gap while the Cranial LOOP (XL) (FC050200) is to be used for covering a standard 14 mm cranial burr hole only.	The Cranial COVER is intended for use to cover burr holes resulting from cranial surgery. With then available sizes, burr holes with an epicranial diameter between 10 and 14 mm, made with standard perforators or with spherical drills, can be covered.
Anatomical site	Same	Burr hole	Cutting line or Burr hole	Burr hole
Device Design	Same	Two platforms linked	Two platforms linked by	Two platforms linked by

		by a bolt, joined with lower platform allowing movement of the upper platform towards the lower platform. The surgeon tightens the upper platform to the bone by gently rotate the driver to covers the burr hole like a plug.	two adjustable cable ties, which are joined to the lower platform and have a locking system that allows movement of the upper platform towards the lower platform but impedes backward movements. The surgeon tightens the lower platform to the bone and bone flap by gently pressing with the applier and pulling on the handle.	two adjustable cable ties, which are joined to the lower platform and have a locking system that allows movement of the upper platform towards the lower platform but impedes backward movements. The surgeon tightens the upper platform to the bone by gently pressing with the applier and pulling on the handle.
Applier Instrument	Same	Not necessary	Not necessary	Not necessary
Material Composition	Same	Platforms (Implantable parts)-PEEK	Platforms and ties (implantable parts) – PEEK	Platforms and ties (implantable parts) – PEEK
Sizes	Same	Various sizes for the system, that available for burr hole of diameter 11/7, 11/8, 13/9, 14/11, 15/12 mm made with standard perforators or 10, 11, 12 mm with spherical drills, can be covered. They can fix skull thicknesses ranging from 3mm to 14mm.	FC050000 and FC050100 applicable in osteotomy line for bone flap fixation. FC050200, only size applicable in burr holes cover. They can fix cranical thicknesses ranging from 4mm to 24mm.	- FC050300: for burr holes of diameter 14/11 mm and 13/9 mm - FC050400: for burr holes of diameter from 10 to 12 mm
Implant life	Same	Long-term implant	Long-term implant	Long-term implant
Biocompatible	Same	Yes	Yes	Yes
Provided Sterile	Same	Yes	Yes	Yes
Sterile Method	Same	Irradiation	Irradiation	Irradiation
MRI Compatibility	Same	MR Safe	MR Safe	MR Safe
Method of Fixation to Cranium	Same	Like a clamp	Like a clamp	Like a clamp

Discussion of mechanical and performance testing

Test	Test Method Summary	Result
A. Functional testing		
A.1. Functionality of the implantable parts	**Goal :** Verification the available sizes for cranial: (A) Burr hole diameter (B) Bone thickness **Method:** Fully assembled devices were tested. Simulated surgery to each size of burr hole diameter and bone thickness.	All tested samples meet the functionality acceptance criteria and relevancy the test result has demonstrated that the technological characteristics of CirFIX® Cranial bone fixation system is substantially equivalent to the predicate devices do not raise any new safety or effectiveness issues.
A.2. Functionality of the implantable parts and the driver	**Goal:** Determine the maximum torque force (breaking force) of the threads mechanism of the driver and upper platforms (Screw). **Method:** Fully assembled devices were tested. A calibrated dynamometer was used to apply a torque force on the driver until platforms or bolt broke.	
B. Biomechanical testing		
B.1. Strength to bone flap compression (Push-in)	**Goal:** Simulate strength to bone flap compression (Push-in) and determine the force required to sink the bone flap up to a maximum of 2 mm. **Method:** A push load was applied to model which simulates the cranium and bone flap with three Flap Fixators representing clinical use.	All tested samples meet the specifications. The devices have an adequate biomechanical behavior at push-in and pull-out. The relevancy of the test results in determining the substantial equivalence of the proposed device.
B.2. Push-in	**Goal:** Simulate patient's pressure on the device and determine the force required to sink the devices up to a maximum of 2 mm. **Method:** Fully assembled devices were tested in holes equivalent to those in which they will be implanted. The implanted devices were placed under a calibrated dynamometer and a cylindrical tool used to apply force on the upper platform.	
B.3. Pull-out	**Goal:** Simulate pulling forces caused by increased ICP, to determine the maximum force that the device can withstand before sliding out from the burr hole.	

	Method: Fully assembled devices were tested in holes equivalent to those in which they will be implanted. A calibrated dynamometer was used to apply a traction force on the button of lower platform until the lower platform slid out from the hole.	
C. Cadaver testing	**Goal:** Evaluation of the devices when simulating their implantation on the skull of patients in a clinical environment, following the procedures described in the products' Instructions for Use. **Method:** The test was performed on two cadaveric specimens with fully assembled devices. Four different craniotomies were tested: ● Frontal-Parietal(Right side) ● Parietal-Temporal (Left side) ● Frontal-Parietal-Temporal(Right side) ● Frontal-Parietal-Sphenoid wing(Left side) Some of the most relevant aspects analyzed include: 1. Sufficient space for device placement. 2. No danger for the surgeon during device application. 3. Correct positioning of the device. 4. Rapid and simple application of the device with minimum instruments. 5. Absence of damage to the dura mater: the tissue will be examined after removal of the device to detect any possible incidence. 6. Easy removal of the system: after implantation. 7. Lateral and axial stability when the device is moved. 8. Low epicranial and subcranial platform profiles. 9. Adaptation to different cranium curvatures. 10. Adaptation to different cranium thicknesses. 11. No artifacts on neuroimaging. 12. Fast and no special tools are required.	Correct implantation is verified in a simulated real-life situation. The devices show adequate performance and safety. The results demonstrate that the CirFIX® Cranial bone fixation system is equivalent, in terms of performance and safety and to the relevant extent, to the predicate devices.