October 21, 2022

MCI Medical Concept Innovation Inc.
% Graziela Brum
Regulatory Affairs Specialist
Passarini Regulatory Affairs/ PR Servicos
Regulatorios Administrativos Ltda ME
Rua Alice Alem Saadi, 855/2402
Ribeirao Preto, Sao Paulo 14096-570
Brazil

Re: K212391
Trade/Device Name: MCI-Neuro Fixation System
Regulation Number: 21 CFR 882.5320
Regulation Name: Preformed Alterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GWO, GXR, HBW
Dated: September 20, 2022
Received: September 21, 2022

Dear Graziela Brum:

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.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212391

Device Name
MCI - Neuro Fixation System

Indications for Use *(Describe)*
MCI - Neuro Fixation System is indicated for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedure.

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.

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510(k) Summary

ADMINISTRATIVE INFORMATION

Sponsor/Manufacturer Name	MCI Medical Concept Innovation Inc. 4592 North Hiatus Road Sunrise, Florida, USA 33351 Telephone +01 (954) 306-2521
Contact Person and Preparer	Graziela Brum and Ana Carolina Carvalho Regulatory Affairs Specialist Passarini Regulatory Affairs PR Serviços Regulatórios Administrativos Ltda E-Mail: graziela@passarini.com.br Telephone +55 (16) 3421-8488
Date Prepared	20/September/2022

DEVICE NAME AND CLASSIFICATION

Trade/ Proprietary Name	MCI - Neuro Fixation System
Common Name	Plate, Cranioplasty, Preformed, Alterable; Cover, Burr Hole; Fastener, Plate, Cranioplasty
Classification Regulation	21 CFR 882.5320
Product Code	GWO, GXR, HBW
Classification Panel	Neurology
Reviewing Branch	Neurology

PREDICATE DEVICE INFORMATION

Predicate Device	**K141911 -** OPTIMUS NEURO SYSTEM
Reference Devices	**K971297 -** CENTRE-DRIVE DRILL-FREE SCREW **K161821-** Stryker Universal Mesh **K141452 -** Leforte Neuro System Bone Plate and Screw **K121624 -** Biomet Microfixation Neuro Plating System **K182758 -** MCI -CMF System **K944565-** KLS-MARTIN Micro Osteosynthesis System (1.5mm)

INDICATIONS FOR USE

MCI - Neuro Fixation System is indicated for use in selective trauma of the cranial skeleton, cranial surgery, and reconstructive procedure.

DEVICE DESCRIPTION

The MCI – Neuro Fixation System is composed of plates (including burr hole covers), screws, and meshes. The bone plates and meshes are made from commercially pure titanium (ASTM F67) and the bone screws are manufactured from titanium alloy - Ti-6Al-4V (ASTM F136) and are available in different sizes and shapes, according to the site of the implantation and the extension of the fracture. The surface of plates, meshes and screws are colored-anodized.

MCI - Neuro Fixation System devices are for single use. The devices are provided non-sterile and must be properly sterilized before use, according to the recommendations provided in the Instructions for Use.

The devices must only be used by qualified surgeons mastering the surgical technique, having been trained and qualified in cranial surgery.

Comparison of Technological Characteristics with the Predicate Device

	SUBJECT DEVICE	**PREDICATE DEVICE**
Device Name	**MCI - Neuro Fixation System**	**Neuro Plating System**
510(K) #	**K212391**	**K141911**
Manufacturer	MCI Medical Concept Innovation Inc.	OPTIMUS NEURO SYSTEM
Indications for use	MCI - Neuro Fixation System is indicated for use in selective trauma of the cranial skeleton, cranial surgery, and reconstructive procedure.	Optimus Neuro System is intended for use in selective trauma of the cranial skeleton, cranial surgery, and reconstructive procedure.
Class	2	2
Product Code	GWO, GRX, HBW	GWO, GRX, HBW
Material (Chemical composition)	▪Plate- Pure Titanium ASTM F67 (Anodized) ▪Screw- Titanium Alloy ASTM F136 (Anodized)	▪Plate- Pure Titanium ASTM F67 (Anodized) ▪Screw- Titanium Alloy ASTM F136 (Anodized)
Device types and Dimension	Straight, Square, Rectangular, Y-shape, X-shape, Z -shape, clover, triangular, mesh, burr hole with various lengths and thickness (03 to 06.mm). The screws range in 1.5 mm diameter to 1.7 mm and in lengths from	Straight, angle, Y-shape, X-shape, burr hole, square, matrix and mesh with various lengths and thickness Plate has various length and thickness (0.1 to 0.6mm). The screws range in diameters of 0.8 to 1.8mm and lengths from 3.0 to 6.0mm.

	3.0mm to 6.0 mm.	
Single Use	Yes	Yes
Sterilization	Nonsterile, steam sterilization before use	Nonsterile, steam sterilization before use

The subject device is substantially equivalent in indications and design principles to the following predicate device: K141911 - OPTIMUS NEURO SYSTEM

Any difference in the technological characteristics do not raise new issues of safety or efficacy.

Performance Data

Test	**Test Method Summary**	**Results**
Metallographic Test	Applied Standard ASTM F67-13. Perform metallography on implant through an Olympus BX41M-LED microscope, with Kroll attack - immersion.	The material complied with the specifications set forth in the applied standard.
Metallographic Test	Applied Standard ASTM F136 -13. Perform metallography on implant through an Olympus BX41M-LED microscope, with Kroll attack - immersion.	The material complied with the specifications set forth in the applied standard.
Cyclic polarization tests	Applied Standard ASTM F2129-19 a. A scan rate of 1,0 mV /s was used increasing from the corrosion potential, after 1 h of open-circuit or a potential variation less than 3 mV in 60 seconds. The scan was reversed to cathodic direction at 800 mVECS or when the current density reaches two orders of magnitude greater than the passivation threshold.	The devices have high resistance to initiation and to the propagation of localized corrosion.
Cycle Bend Testing of Metallic Bone Plates	Applied Standard ASTM F382-17 Annex A.1. Testing machine: Universal Testing Machine. The test was performed in ambient conditions (ambient air at room temperature. **OBJECTIVE:** To determine the following four-point bending properties (static) of metallic bone plate:	The Structural Stiffness (Ele) of a bone plate, is the bone plate normalized effective bending stiffness. The test reports showed a Structural Stiffness of 0.003 Nm^2 for the subject and reference devices. The Bending Stiffness (K) of a bone plate, is the maximum slope of the linear elastic portion of the load versus load-point displacement curve. The test reports show that the reference device plate Bending Stiffness was 70.4

	- Structural Stiffness - Stiffness - Bending Strength - Proof Load	N/mm and to the subject device plate 75.7 N/mm. The Bending Strength (R) of a bone plate, is the bending moment necessary to produce a 0.2 % offset displacement in the bone plate when tested as the standard prescription. The test reports showed a Bending Strength of 0.04 Nm for the subject and reference devices. The proof load (P) is the applied load at the intersection point of line. BC with the load versus load-point displacement curve. The test reports show a reference device plate Proof Load of 16.08 N and to the subject device plate of 15.74 N. The above results allow the conclusion that the subject device worst case plate proved to be slightly stiffer and mechanically resistant than the reference device K944565 and therefore, can be considered equivalents for the performance standpoint.
Screw Torsion yield Test	Applied Standard ASTM F543-17 Annex A.1. Testing machine: Torsion Equipment. The test was performed in ambient conditions (ambient air at room temperature. **OBJECTIVE:** To determine the following torsional properties of bone screw: Torsional Yield Strength Maximum Torque According to the ASTM F543-17 Standard, the specimen needs to be placed in the holding device so that five threads, below the head of the screw, are exposed outside the holding device. The screws that were evaluated do not attend this condition because they are too small. So, the “Breaking Angle”	The table A5.5 of the standard ASTM F543-17 - Standard Specification and Test Methods for Metallic Medical Bone Screws establish that the Screw type 1.5 should presents minimum Torsional Strength of 0.2 Nm. The worst case of the device in question and the reference device K944565 met the requirement of the applied standard. The Torsion test reports show the reference device screws presented a maximum torque 0.28 Nm, while the subject screws presented a maximum torque of 0.29 Nm. Both tested screws (subject and reference device) accomplish the standard requirements and therefore can be considered equivalents.

	request is not applicable in this case.	
Pull out testing	Applied Standard ASTM F543-17 Annex A.3. **OBJECTIVE:** Determine axial pullout strength of bone screw	The test reports show for the reference device screw a maximum force of 46.71 N, and for the subject device screw of 45.54 N. A maximum force variation of less than 2.5% was observed between reference and subject device and therefore they were considered equivalent.
Driving torque testing	Applied Standard ASTM F543-17 Annex A.2. **OBJECTIVE:** To determine the driving torque of bone screw Testing machine: Torsion Equipment. The test was performed in ambient conditions (ambient air at room temperature.	The driving torque testing shows for the subject device an insertion torque of 0.05 Nm and a removal torque of 0.02 Nm. The reference device has presented an insertion and removal torque of 0.09 Nm and 0.03 Nm, respectively. For both cases, subject and reference, the insertion and removal torque are below than the Torsional Yield Strength. Therefore, considering the overall results of mechanical performance, the behavior of the subject and reference device can be deemed equivalent.

Biocompatibility of the subject devices are supported by the reference device K182758.

No clinical data were included in this submission.

The subject devices are provided non-sterile and have no expiration date defined.

CONCLUSION

The documentation submitted in this premarket notification demonstrates that the subject devices have equivalent features and performance and, therefore, are substantially equivalent to the identified predicate device.