December 21, 2021

Meticuly Co., Ltd.
Peeranoot Lohwongwatana
Managing Director
32/77, Soi Samakkee 58/20, Samakkee rd., Tasai
Muang Nonthaburi, Nonthaburi 11000, Thailand

Re: K210099
Trade/Device Name: Meticuly Patient-Specific Titanium Mesh Implant
Regulation Number: 21 CFR 882.5330
Regulation Name: Preformed Nonalterable Cranioplasty Plate
Regulatory Class: Class II
Product Code: GXN
Dated: November 17, 2021
Received: November 22, 2021

Dear Peeranoot Lohwongwatana:

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)*
K210099

Device Name
Meticuly Patient-specific Titanium Mesh Implant

Indications for Use *(Describe)*
Meticuly patient-specific titanium mesh implant is a device that is designed individually for each patient. This device is intended for use in selective trauma of the cranial and craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, parietal bone, sphenoid bone, supraorbital process, vomer), cranial and craniofacial surgery, and reconstructive procedures.

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 K210099

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary of the K210099 Meticuly Patient-Specific Titanium Mesh Implant:

1. Submitter Information

Company/Applicant:
Mrs. Peeranoot Lohwongwatana
Managing Director
Meticuly Co., Ltd.
924 B bldg., Rm. B116-118, B210-212
Soi Chula 7, Wang Mai, Pathum Wan
Bangkok, Thailand 10330
Telephone: +6688-834-7777
Email: peeranoot@meticuly.com

Contact:
Paweena U-Thainual, PhD
MDR Solutions Co., Ltd.
1435, Kanjanapisek Rd., Bang Khae Nuea
Bang Khae, Bangkok 10160 Thailand
Telephone: +662-804-2101
Email: paweena@mdrsolutions.co.th

Date Summary Prepared: December 13, 2021

2. Device Name

Trade Name:	Meticuly Patient-Specific Titanium Mesh
Common Name:	Implant Preformed Nonalterable Cranioplasty
Classification Name:	Plate Neurology
Review Panel:	Neurology (NE)
Regulation:	882.5330
Class:	Class II
Product Code:	GXN

3. Predicate Device

Meticuly Patient-specific Titanium Mesh Implant is substantially equivalent to the following legally marketed predicate device:

Table 1.1 Primary Predicate device

Applicant	Device Name	510(k) Number
Jeil Medical Corporation	LaForte Neuro System Bone Plate and Screw	K141452

Table 1.2 Reference device*

Applicant	Device Name	510(k) Number
BioArchitects USA, LLC.	BioArchitects Patient Specific Cranial/Craniofacial Plate	K151692

*This device is referred to support the use of a similar material and manufacturing for the subject device

4. Description

Meticuly's Patient-specific Titanium Mesh Implant is a device designed individually to replace each patient's bony voids in the cranial and/or craniofacial skeleton. The craniofacial skeleton comprises of frontal bone, temporal bone, occipital bone, parietal bone, sphenoid bone, supraorbital process, vomer. This patient-specific device is intended to be used with titanium screws. The subject device has been validated and tested with titanium screws with the diameter of 1.4 mm - 1.8 mm (K141452 : Jeil Medical's LeForte Neuro system screws). The implant is made of titanium alloys produced via additive manufacturing (Laser Powder Bed Fusion). The surgeon approves the design of the mesh implant prior to fabrication of the implant device.

5. Indications for Use

Meticuly Patient-specific Titanium Mesh Implant is a device that is designed individually for each patient. This device is intended for use in selective trauma of the cranial and craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, parietal bone, sphenoid bone, supraorbital process, vomer), cranial and craniofacial surgery, and reconstructive procedures.

6. Comparison of Technological Characteristics with the Predicate Device

The subject device is substantially equivalent to the following legally marketed predicate devices. Meticuly Patient-specific Titanium Mesh Implant and the predicate devices have the similar characteristics, for example, indication for use, intended use, sterilization method, material, manufacturing method, device design, and device performance. The differences of these characteristics have been addressed with the provided performance test data in this submission and do not raised different questions of safety and effectiveness.

Table 2: Technical Characteristics in Comparison to the Predicate and Reference Devices			
Device comparison	Subject Device: Meticuly Patient-specific Titanium Mesh Implant	Predicate Device: LeForte Neuro System Bone Plate and Screw	Reference Device: BioArchitects Patient Specific Cranial/Craniofacial Plate
510(K) number	K210099	K141452	K151692
Product Code(s)	GXN	GWO, GXR, HBW	GXN

Table 2: Technical Characteristics in Comparison to the Predicate and Reference Devices			
Device comparison	Subject Device: Meticuly Patient•specific Titanium Mesh Implant	Predicate Device: LeForte Neuro System Bone Plate and Screw	Reference Device: BioArchitects Patient Specific Cranial/Craniofacial Plate
Classification	Class II	Class II	Class II
Indications for Use	Meticuly Patient-specific Titanium Mesh Implant is a device that is designed individually for each patient. This device is intended for use in selective trauma of the cranial and craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, parietal bone, sphenoid bone, supraorbital process, vomer), cranial and craniofacial surgery, and reconstructive procedures.	This device is intended for use in selective trauma of the cranial skeleton, cranial surgery and reconstructive procedures.	The BioArchitects Patient Specific Cranial/Craniofacial Plate implant device is intended to replace bony voids in the cranial and/or craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, nasal bone, parietal bone, supraorbital process, lacrimal bone, zygomatic bone, sphenoid bone, ethmoid process, vomer). It is a patient specific device.
Material(s)	Titanium Ti•6Al•4V ELI (Grade23)	Commercially pure Titanium	Titanium alloy (Ti•6Al•4V ELI)
Technical Specifications	Custom-made to each patient using CT data	Custom sized to each patient	Custom-made to each patient using CT or MRI data
Manufacturing Method	3D printed using laser powder bed fusion additive manufacturing	Machined and surface treated by anodization	3D printed using electron beam melting additive manufacturing
Fixation Method	Commercially available titanium screws systems	Own plate and screw system	Commercially available titanium screws systems
Sterilization	Non-sterile	Non-sterile	Non-sterile

7. Performance Tests

Materials and manufacturing method quality of Meticuly Patient-specific Titanium Mesh Implant were assessed through physical properties and mechanical properties. The device testing was designed to validate the manufacturing process and to ensure that the subject device complies with the applicable voluntary consensus standards for biocompatibility, packaging, transportation, and sterilization. Verification and validation testing confirms that the product specifications have been met, demonstrating that the device will perform as intended. There were no unexpected results which indicate the suitable material used and manufacturing process compared to the standards for medical devices.

Table 3: Testing and compliance standards summary table	
Test	**Standard (FDA recognition number)**
Materials and manufacturing method	ASTM F3001-14 (8-439) Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) with Powder Bed Fusion
Biological evaluation and Biocompatibility	ASTM F756-17 Standard Practice for Assessment of Hemolytic Properties of Materials ISO 10993-1 Fourth edition 2009-10-15 (2-220) Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including: Technical Corrigendum 1 (2010)] ISO 10993-3 Third edition 2014-10-1 (2-228) Biological evaluation of medical devices - Part 3:Tests for genotoxicity carcinogenicity and reproductive toxicity ISO 10993-4:2017 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood ISO 10993-5 Third edition 2009-06-01 (2-245) Biological evaluation of medical devices - Part 5:Tests for in vitro cytotoxicity ISO 10993-6 Third edition 2016-12-01 (20247) Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation ISO 10993-10 Third Edition 2010-08-01 (2-174) Biological evaluation of medical devices - Part 10:Tests for irritation and skin sensitization ISO 10993-11 Third edition 2017-09 (2-255) Biological evaluation of medical devices - Part 11: Tests for systemic toxicity

Table 3: Testing and compliance standards summary table	
Test	**Standard (FDA recognition number)**
Sterilization process control and validation	ANSI AAMI ST72:2011/(R)2016 (14-360) Bacterial endotoxins - Test methods routine monitoring and alternatives to batch testing USP 42-NF37:2019 <85> Bacterial Endotoxins Test (14-533) USP 42-NF37:2019 <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests (14-534) ISO 17665-1 First edition 2006-08-15 (14-333) Sterilization of health care products - Moist heat - Part1: Requirements for the development validation and routine control of a sterilization process for medical devices ISO 11737-1 Third edition 2018-01 (14-514) Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on product ISO 11737-2 Third edition 2019-12 (14-540) Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition validation and maintenance of a sterilization process
Packaging and transportation control and validation	ASTM F88/F88M-15 (14-482) Standard Test Method for Seal Strength of Flexible Barrier Materials ASTM D7386-16 (5-113) Standard Practice for Performance Testing of Packages for Single Delivery Systems

8. Pre-clinical performance test

The Meticuly Patient-specific Titanium Mesh Implant was mechanically tested for tensile and elastic strength, with test results similar to those of predicates. The performance of the subject device was assessed through three comparative tests. According to the results, the Meticuly Patient-specific Titanium Mesh Implant is considered substantially equivalent to the predicate device.

Table 4: Performance testing summary table		
Test	**Test method summary**	**Results**
Comparative device modeling with Finite Element Analysis (FEA)	Computational simulation was performed with a compression load in the normal direction on the center of the mesh implant. The load was applied on the surface of the implant. This static loading represents a simulation of a relaxed person resting on a pillow.	The FEA consideration is based on maximum equivalent stress, safety factor and maximum deformation. The result of the comparative test shows that the subject device is substantially equivalent to the predicate device.
Comparative mechanical testing with modified compression test	- The subject device and the predicate device were designed or shaped into a similar design. Both subject device and predicate device were fixated onto the plastic anatomic model that represented the skull with screws. - Compression test was performed under the displacement control to maximum displacement in the normal direction on the center of the mesh implant.	The mechanical consideration is based on the stiffness and energy absorption. The result of the comparative test shows that the subject device is substantially equivalent to the predicate device.
Comparative roughness testing via non-contact method	The surface roughness evaluation was performed following the ISO 4288 and ISO 25178.	The result of the comparative test shows that the subject device is substantially equivalent to the predicate device.
Device fidelity and validation of device dimensional fit	Confirm the design qualification and fidelity of the device with the quality instruments.	The results show the fidelity of the device and the traceability between the CT scan data and the final product.

9. Conclusion

Based upon testing and comparison to the predicate device, the Meticuly Patient-specific Titanium Mesh Implant has the same intended use and similar technological characteristics. The device performs as intended and does not raise new questions of safety or effectiveness; Thus, the subject device is concluded to be substantially equivalent to the legally commercialized predicate devices for the purposes of this 510(k) submission.