January 14, 2026

Meticuly Co., Ltd.
% Paweena U-Thainual
CEO
MDR Solutions Co., Ltd.
1435 Kanjanapisek Road
Bang Khae Nuea, Bang Khae
Bangkok, 10160
Thailand

Re: K252958
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: December 8, 2025
Received: December 8, 2025

Dear Paweena U-Thainual:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JULIA E. SLOCOMB -S

Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.01.14 13:27:23 -05'00'

for Jaime Raben, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252958

Please provide the device trade name(s).

METICULY Patient-specific titanium mesh implant

Please provide your Indications for Use below.

METICULY Patient-specific titanium mesh implant is a device that is designed individually for each patient. This device is indicated for reconstruction of bony defects resulting from selective trauma of the cranial and craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, parietal bone, sphenoid bone, supraorbital process, vomer) during cranial and craniofacial surgery and reconstructive procedures.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary of the METICULY Patient-specific titanium mesh implant:

1. Submitter Information

Company/Applicant:

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Date Summary Prepared: September 4, 2025

2. Device Name

Trade Name:	METICULY Patient-specific titanium mesh implant
Common Name:	Preformed nonalterable cranioplasty plate
Review Panel:	Neurology
Regulation:	882.5330
Classification:	Class II
Product Code:	GXN

3. Predicate Device

METICULY Patient-specific titanium mesh implant is substantially equivalent to the following legally marketed predicate devices.

Table 1.1 Primary Predicate device

Applicant	Device Name	510(k) Number
Meticuly Co., Ltd.	METICULY Patient-specific titanium mesh implant	K210099

Table 1.2 Reference devices*

Applicant	Device Name	510(k) Number
Meticuly Co., Ltd.	METICULY Patient-specific titanium maxillofacial mesh implant	K232889

*These devices are referred to support the use of similar material and manufacturing for the subject device.

4. Description

METICULY Patient-specific titanium mesh implant is a device designed individually to replace each patient's bony defects (bony voids and/or bone deformities) in the cranial and/or craniofacial skeleton. The craniofacial skeleton comprises the frontal bone, temporal bone, sphenoid bone, parietal bone, occipital bone, supraorbital process and vomer bone. This patient-specific device is intended to be used with titanium screws. The implant is made of titanium alloys produced via additive manufacturing (Laser Powder Bed Fusion). The FDA-cleared commercially available titanium screws that can be used with the subject devices include the Jeil Medical's LeForte Neuro System screws (K141452), the Titanium miniplate system (K951690) and Micro titanium plate system (K951688). 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 indicated for reconstruction of bony defects resulting from selective trauma of the cranial and craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, parietal bone, sphenoid bone, supraorbital process, vomer) during 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 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 raise 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: METICULY Patient-specific titanium mesh implant	Reference Device: METICULY Patient-specific titanium maxillofacial mesh implant
510(K) number	K252958	K210099	K232889
Product Code(s)	GXN	GXN	JEY
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 indicated for reconstruction of bony defects resulting from selective trauma of the cranial and craniofacial skeleton (e.g., frontal bone, temporal bone, occipital bone, parietal bone, sphenoid bone, supraorbital process, vomer) during cranial and craniofacial surgery and reconstructive procedures.	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.	METICULY Patient-specific titanium maxillofacial mesh implant is intended for bone fixation and reconstruction, restoration of bone defects and intended to provide continuity in regions where the bone is missing and/or to augment the bone by means of an onlay device in the maxillofacial skeleton and midface.
Material(s)	Implant: Titanium Ti-6Al-4V ELI(Grade23)	Implant: Titanium Ti6Al4V ELI (Grade23)	Implant: Titanium Ti6Al4V ELI (Grade23)
Technical Specifications	Custom-made to each patient using CT data	Custom-made to each patient using CT data	Custom-made to each patient using CT data
Manufacturing Method	3D printed using laser powder bed fusion additive manufacturing	3D printed using laser powder bed fusion additive manufacturing	3D printed using laser powder bed fusion additive manufacturing
Fixation Method	Commercially available titanium screws systems	Commercially available titanium screws systems	Commercially available titanium screws systems
Sterilization	Non-sterile	Non-sterile	Non-sterile
Dimension	Length: 20 – 200 mm Width: 20 – 210 mm	Length: 20 – 105 mm Width: 20 – 105 mm	OrbiMesh Length: 10 – 100mm

	Height: 0.4 – 130 mm	Height: 0.4 – 125 mm	Width: 10 – 90 mm Height: 0.4 – 125mm FaciMesh Length: 10 – 120mm Width: 10 – 100 mm Height: 0.4 – 125mm
Overall Thickness	0.4 – 0.9 mm	0.4 – 0.9 mm	OrbiMesh 0.4 – 0.9 mm FaciMesh 0.4 – 0.9 mm
Screw Diameter	1.4 – 2.3 mm	1.4 – 1.8 mm	1.5 – 2.3 mm
Plate Holes	Non-locking	Non-locking	Non-locking
MR Label	MR conditional	MR unsafe	MR unsafe

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 indicated 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	ISO 10993-1 Fifth edition 2018-08 (2-258) Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process 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 Third edition 2017-04 (2-248) 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 (2-247) Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation ISO 10993-10 Fourth edition 2021-11 (2-296) Biological evaluation of medical devices - Part 10: Tests for skin sensitization ISO 10993-11 Third edition 2017-09 (2-255) Biological evaluation of medical devices - Part 11: Tests for systemic toxicity ISO 10993-23 First Edition 2021-01 (2-291) Biological evaluation of medical devices - Part 23: Tests for irritation

Table 3: Testing and compliance standards summary table	
Test	**Standard (FDA recognition number)**
Sterilization process control and validation	ANSI AAMI ST72:2019 (14-541) Bacterial endotoxins - Test methods routine monitoring and alternatives to batch testing USP-NF M98830_02_01 <85> Bacterial Endotoxins Test (14-570) USP-NF M98910_01_01 <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests (14-564) USP-NF M98810_01_01 <71> Sterility Tests (14-569) ISO 17665-1 First edition 2024-03 (14-601) Sterilization of health care products - - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices. ISO 11737-1 Third edition 2018-01 [Including AMD1:2021] (14-577) 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 ISO 19227 First edition 2018-03 (11-348) Implants for surgery - Cleanliness of orthopedic implants - General requirements
Packaging and transportation control and validation	ASTM F88/F88M-23 (14-596) 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 F1886/F1886M-16 (14-501) Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection

	F1929-23 (14-600) Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

8. Performance Bench 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.

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.