April 30, 2024

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

Re: K232889
Trade/Device Name: METICULY Patient-specific titanium maxillofacial mesh implant
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: August 21, 2023
Received: April 1, 2024

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.

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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and

ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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)*
K232889

Device Name
METICULY Patient-specific titanium maxillofacial mesh implant

Indications for Use *(Describe)*
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.

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.

510(k) Summary – K232889

The following information is provided in accordance with 21 CFR 807.92 for the Premarket 510(k) Summary of the METICULY Patient-specific titanium maxillofacial 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 Email: paweena@mdrsolutions.co.th
Date Summary Prepared:	April 30, 2024

2. Device Name

Trade Name:	METICULY Patient-specific titanium maxillofacial mesh implant
Common Name:	Plate, Bone
Classification Name:	Bone Plate
Review Panel:	Dental
Regulation:	872.4760
Class:	Class II
Product Code:	JEY

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3. Predicate Device

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

Table 1.1 Primary Predicate device

Applicant	Device Name	510(k) Number
Materialise NV	TruMatch CMF Titanium 3D Printed Implant	K173039

Table 1.2 Reference devices*

Applicant	Device Name	510(k) Number
KLS-Martin L.P.	KLS Martin Individual Patient Solutions	K191028
Meticuly Co., Ltd.	METICULY Patient-specific Titanium Mesh Implant	K210099
Jeil Medical Corporation	LeForte System Bone Plate & Screw	K112457

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

4. Description

The METICULY Patient-specific titanium maxillofacial mesh implant is a device designed individually for each patient and intended for use in selective trauma of the maxillofacial skeleton, maxillofacial surgery, and reconstructive procedures. It is specifically designed with a focus on applications of non-bending related scenarios. The implant is made of titanium alloys produced via additive manufacturing (Laser Powder Bed Fusion) and is intended to be used with titanium screws. All additive manufacturing and other post-processing steps are only to take place under Meticuly manufacturing control. The device is not intended to substitute for bone reconstruction in clinical situations where bone is needed for support and stability of the maxillofacial skeleton under functional loading conditions. It is intended for adults only (at least 22 years of age). The surgeon approves the design of the mesh implant prior to fabrication of the implant device by the sponsor. The proposed FaciMesh models are intended to treat the maxillofacial region, while the OrbiMesh models treat the Orbital region. The device is not intended for reconstruction of the orbital roof defects or for any frontal bone defects, such as the supra-orbital ridge. Additionally, the FDA-cleared commercially available titanium screws that can be used with the subject devices include the TITANIUM MINIPLATE SYSTEM (K951690) and MICRO TITANIUM PLATE SYSTEM (K951688).

5. Indications for Use

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.

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 maxillofacial 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 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 maxillofacial mesh implant	Predicate Device: TruMatch CMF Titanium 3D Printed Implant	Reference Device: LeForte System Bone Plate & Screw	Reference Device: METICULY Patient-specific titanium mesh implant	Reference Device: KLS Martin Individual Patient Solutions
510(K) number	K232889	K173039	K112457	K210099	K191028
Product Code(s)	JEY	JEY	JEY	GXN	JEY
Classification	Class II	Class II	Class II	Class II	Class II
Indications for use	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.	The TruMatch CMF Titanium 3D Printed Implant is a patient specific implant and 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, midface and chin.	This device is intended for use in selective trauma of the mid-face, reconstruction procedures and selective orthognathic surgery of the maxilla and chin.	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.	KLS Martin Individual Patient Solutions implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions.
Material(s)	Titanium Ti-6Al-4V ELI (Grade23)	Commercially pure titanium	pure Titanium (ASTM F67 Grades 1,2, and 3)	Titanium Ti6Al4V ELI (Grade23)	Titanium (ASTM F67) or Ti-6Al-4V (ASTM F136)
Technical Specifications	Custom-made to each patient using CT data	Custom-made to each patient using CT data	Commercially sized	Custom-made to each patient using CT data	Custom-made to each patient using CT data

Table 2: Technical Characteristics in Comparison to the Predicate and Reference Devices					
Device comparison	Subject Device: METICULY Patient-specific titanium maxillofacial mesh implant	Predicate Device: TruMatch CMF Titanium 3D Printed Implant	Reference Device: LeForte System Bone Plate & Screw	Reference Device: METICULY Patient-specific titanium mesh implant	Reference Device: KLS Martin Individual Patient Solutions
Manufacturing Method	3D printed using laser powder bed fusion additive manufacturing	Additive manufacturing, Selective Laser Melting	Machined and surface treated by anodization	3D printed using laser powder bed fusion additive manufacturing	Epoxy/ Acrylic Resins: Stereolithography (SLA) CP Titanium: Traditional(Subtractive) Ti-6A1-4V: Traditional and 3D (Additive; Selective Laser Melting)
Fixation Method	Commercially available titanium screws systems	Commercially available titanium screws system (Synthes)	Own plate and screw system	Commercially available titanium screws systems	Own plate and screw system
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Plate Dimension	OrbiMesh Length: 10-100 mm Width: 10-90 mm Height: 0.4-125 mm FaciMesh Length: 10-120 mm Width: 10-100 mm Height: 0.4-125 mm	Length: 10-294mm Width: Unknown Height: Unknown	Length: 5.2-223.5 mm Width: Unknown Height: 4.2 – 46.8 mm	Length: 20 - 105 mm Width: 20 - 105 mm Height: 0.4 - 125 \mm	Length: 18-350 mm Width: Min: ≥ 4.5 mm (around screw holes) Min: ≥ 3 mm (not around screw hole) Max: Dependent on screw-hole Height: Unknown
Overall Thickness	OrbiMesh 0.4 – 0.9 mm FaciMesh 0.4 – 0.9 mm	0.4–10 mm	0.2-2.5 mm	0.4-0.9 mm	Orbital: 0.3-1.0 mm Maxillofacial / Midface: 0.6-10.0 mm
Internal angle at edge boundary	45-180 deg	0-12 deg/mm length	Unknown	45-180 deg	In Plane: 30-180 deg Out of Plane: 15-180 deg
Plate Holes	Non-locking	Unknown	Non-locking	Non-locking	Locking threads optional
Screw Diameter	1.5-2.3 mm	Unknown	0.7-1.6 mm	1.4-1.8 mm	1.5-2.3 mm

Table 2: Technical Characteristics in Comparison to the Predicate and Reference Devices					
Device comparison	Subject Device: METICULY Patient-specific titanium maxillofacial mesh implant	Predicate Device: TruMatch CMF Titanium 3D Printed Implant	Reference Device: LeForte System Bone Plate & Screw	Reference Device: METICULY Patient-specific titanium mesh implant	Reference Device: KLS Martin Individual Patient Solutions
Screw Length	4.0-7.0 mm	Unknown	4.0-18.0 mm	3.0-4.0 mm	3.5-22 mm

7. Performance Tests

The submission provided validation information to support the use of the leftover powder material recycling/reuse between print runs based on representative testing that evaluated maintained chemical composition, particle size, flowability, density, and visual characteristics within the same acceptance criteria ranges as virgin powder. Testing has been provided to show that the density of printed samples representative of the subject devices is consistently within the same acceptance criteria throughout a comprehensive array of build plate locations. Dynamic fatigue strength testing of the subject device to account for the worst-case consideration of print orientation. Validation testing was provided to demonstrate the printed patient-matched device form output consistently matches the digital design and CT scan data inputs under the representative manufacturing conditions across a repeatable process. According to the results, the METICULY Patient-specific titanium maxillofacial mesh implant is considered substantially equivalent to the predicate device.

Materials and manufacturing method quality of METICULY Patient-specific titanium maxillofacial 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. The device was validated using the Overkill method for steam sterilization with moist heat at 135°C for 10 minutes to achieve a SAL of 10^{-6}.

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	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)

Table 3: Testing and compliance standards summary table	
Test	**Standard (FDA recognition number)**
	Biological evaluation of medical devices - Part 3:Tests for genotoxicity carcinogenicity and reproductive toxicity 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 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 ISO 10993-23 First Edition 2021-01 (2-291) Biological evaluation of medical devices - Part 10:Tests for irritation USP-NF M98900_01_01 (2-295) <151> Pyrogen Test (USP Rabbit Test)
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 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

Table 3: Testing and compliance standards summary table	
Test	**Standard (FDA recognition number)**
	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 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-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 F1886/F1886M-16 (14-501) Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection F1929-15 (14-484) Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

8. 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. Thus, the subject device is concluded to be substantially equivalent to the legally commercialized predicate devices for the purposes of this 510(k) submission.