July 25, 2026

Meticuly Co., Ltd.
% Paweena U-Thainual
CEO
Mdr Solutions Co., Ltd.
1435 Kanjanapisek Rd.
Bang Khae Nuea, Bang Khae
Bangkok, 10160
THAILAND

Re: K253206
Trade/Device Name: METICULY Patient-specific CMF solution
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZJ, LLZ
Dated: June 26, 2026
Received: June 26, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Sherrill Lathrop Blitzer

Andrew Steen
for 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

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.	K253206

Please provide the device trade name(s).

METICULY Patient-specific CMF solution

Please provide your Indications for Use below.

METICULY Patient-specific CMF solution is intended to serve as a preoperative software system for simulating /evaluating surgical treatment options. It functions as a software and image segmentation system to transfer imaging data from medical scanners, such as a CT-based system. The input data file is processed by the METICULY system to produce output data files. These files may be provided as digital models or used as input in the manufacturing portion of the system to create physical outputs including implants, surgical guides, bone models, splints, and case reports for use in the maxillofacial, midface and mandibular surgery.

METICULY Patient-specific CMF solution implant devices are intended for use in the stabilization, fixation, and reconstruction of maxillofacial / midface and mandibular skeletal regions in adolescents (12 years of age - 21 years of age) and adults.

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 CMF solution:

1. Submitter Information

Company/Applicant: Mrs. Peeranoot Lohwongwatana
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Date Summary Prepared: July 25, 2026

2. Device Name

Trade Name:	METICULY Patient-specific CMF solution
Common Name:	System used to plan & fabricate patient-specific bone plates, anatomical models, cutting/marking guides, splints, and case reports
Review Panel:	Dental
Regulation:	872.4760
Classification:	Class II
Product Code:	JEY
Subsequent Product Codes:	DZJ, LLZ

3. Predicate Device

METICULY Patient-specific CMF solution is substantially equivalent to the following legally marketed predicate devices.

Table 1.1 Primary Predicate device

Applicant	Device Name	510(k) Number
KLS-Martin L.P.	KLS Martin Individual Patient Solutions	K210731

Table 1.2 Reference devices*

Applicant	Device Name	510(k) Number
PATTON, BOGGS & BLOW	KLS Martin Mini Osteosynthesis System	K943347
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

The METICULY Patient-Specific CMF solution includes software and additive manufacturing equipment used to create outputs for reconstructive and orthognathic surgeries of the midface, maxillofacial region, and non-continuity mandibular segments. The system uses patient-specific anatomical data derived from medical imaging, along with surgeon input, to enable preoperative planning and surgical simulation. It generates customized digital and physical outputs, including patient-specific implants, surgical guides, bone models, splints, and case reports, to assist in the accurate execution of the surgical plan.

5. Indications for Use

METICULY Patient-specific CMF solution is intended to serve as a preoperative software system for simulating /evaluating surgical treatment options. It functions as a software and image segmentation system to transfer imaging data from medical scanners, such as a CT-based system. The input data file is processed by the METICULY system to produce output data files. These files may be provided as digital models or used as input in the manufacturing portion of the system to create physical outputs including implants, surgical guides, bone models, splints, and case reports for use in the maxillofacial, midface and mandibular surgery. METICULY Patient-specific CMF solution implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions in adolescents (12 years of age - 21 years of age), and adults.

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 CMF solution and the predicate devices have same 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.

Similarities to Predicate & Reference Devices

The METICULY Patient-specific CMF solution and the predicate device are patient-specific systems intended to support virtual surgical planning and the stabilization, fixation, and reconstruction of the maxillofacial, midface, and mandibular skeletal regions. Both systems utilize patient CT/CBCT imaging data to generate customized devices for surgical planning and treatment.

The subject device and the predicate device employ validated software systems to process medical imaging data and generate patient-specific digital designs. These designs are used to manufacture customized implants, surgical guides, bone models, splints, and reports.

The subject device shares the same fundamental technological principles as the predicate and reference devices. Patient-specific implants and surgical guides are manufactured from Ti-6Al-4V titanium alloy using additive manufacturing, whereas patient-specific bone models and surgical splints are fabricated from biocompatible polymer materials through additive manufacturing.

The subject device also applies the same fixation concept as the predicate and reference devices by securing customized implants to the maxillofacial skeleton using titanium bone screws. The implant design parameters, including fixation method, overall plate dimensions, curvature, and screw-hole configuration, are within the technological scope of the predicate device.

Both the subject device and predicate devices are supplied non-sterile and are intended to be cleaned and sterilized by the user prior to implantation in accordance with validated processing instructions.

Differences to Predicate & Reference Devices

The subject device is indicated for adolescents and adults, whereas the predicate device also includes pediatric patients younger than 12 years of age. In addition, the subject device is intended for maxillofacial, midface and mandibular non-continuity defects, while the predicate device additionally includes mandibular continuity defects.

The subject device is designed for use with commercially available FDA-cleared titanium screw systems rather than a proprietary screw system. Compatibility with these screw systems has been verified through device validation and performance testing.

Certain implant specifications, including plate thickness, width, and screw size ranges. These differences remain

within the overall technological scope of the predicate device and do not alter the intended fixation principle. The subject device utilizes non-locking titanium screws, while the predicate device includes both locking and non-locking screw options. This difference does not affect the intended fixation method or mechanical performance. These characteristic differences were evaluated through comprehensive non-clinical performance testing, including material characterization, mechanical bench testing, finite element analysis (FEA), and modified compression testing. The results demonstrate that these differences do not raise new questions of safety or effectiveness.

The technological characteristics of the subject, predicate, and reference devices are compared in the table below:

Table 2: Technical Characteristics in Comparison to the Predicate and Reference Devices

Device comparison	Subject Device: METICULY Patient-specific CMF solution	Predicate Device: KLS Martin Individual Patient Solutions	Reference Device: KLS Martin Mini Osteosynthesis System	Reference Device: METICULY Patient-specific titanium maxillofacial mesh implant
510(K) number	-	K210731	K943347	K232889
Product Code(s)	JEY, DZJ, LLZ	JEY, DZJ, LLZ	JEY	JEY
Classification	Class II	Class II	Class II	Class II
Indications for use	METICULY Patient-specific CMF solution is intended to serve as a preoperative software system for simulating /evaluating surgical treatment options. It functions as a software and image segmentation system to transfer imaging data from medical scanners, such as a CT-based system. The input data file is processed by the METICULY system to produce output data files. These files may be provided as digital models or used as input in the manufacturing portion of the system to create physical outputs including implants, surgical guides, bone models, splints, and case reports for use in the maxillofacial,	KLS Martin Individual Patient Solutions (IPS) is intended as a pre-operative software tool for simulating / evaluating surgical treatment options as a software and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the IPS software and the result is an output data file that may then be provided as digital models or used as input in an additive manufacturing portion of the system that produces physical outputs including implants, anatomical models, guides, splints, and case reports for use in maxillofacial, midface, & mandibular surgery.	The KLS Martin Mini Osteosynthesis System is intended for use in the stabilization and fixation of mandibular fractures and oral-maxilla-cranio-facial surgery. The bone segments are attached to the plate with screws to prevent movement of the segments.	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.

	midface and mandibular surgery. METICULY Patient-specific CMF solution implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions in adolescents (12 years of age - 21 years of age), and adults.	KLS Martin Individual Patient Solutions (IPS) implant devices are intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions in children (2 years of age to < 12 years of age), adolescents (12 years of age - 21 years of age), and adults.		
Material(s)	Implants: Titanium Ti-6Al-4V ELI (Grade23) Surgical guides: Titanium Ti-6Al-4V ELI (Grade23) Splints (optional): Photopolymer resins Bone Models: Photopolymer resins, Polyamide	Implants: Ti-6Al-4V or CP Titanium Surgical guides: Polyamide, Ti-6Al-4V, CP Titanium Splints: Acrylic/Methacrylic/Photopolymer resins, Ti-6Al-4V Bone Models: Epoxy/Acrylic resins	Implants: CP Titanium or Ti-6Al-4V	Implants: Titanium Ti-6Al-4V ELI (Grade23) Bone models: Polyamide
Technical Specifications	Custom-made to each patient using CT data	Custom-made to each patient using CT data	No	Custom-made to each patient using CT data
Manufacturing Method	3D printed using laser powder bed fusion additive manufacturing	Epoxy/Acrylic Resins: Additive; Stereolithography (SLA) CP Titanium: Traditional (Subtractive) Ti-6Al-4V: Additive; Selective Laser Melting (SLM) & Traditional (Subtractive) Acrylic/methacrylic resins: 3D printing - (DLP) Photopolymer resins: 3D printing - (cDLM)	CP Titanium or Ti-6Al-4V: Traditional (Subtractive – Milling)	3D printed using laser powder bed fusion additive manufacturing
Fixation Method	Commercially available titanium	Own screw system	Own screw system	Commercially available titanium screws systems

	screws systems			
Sterilization	Non-sterile	Non-sterile	Non-sterile	Non-sterile
Length	Maxillofacial/ midface: Min: 18 mm Max: 350 mm Mandibular (non-continuity defects): Min: 18 mm Max: 350 mm	Maxillofacial/ midface: Min 18 mm Max: 350 mm Mandibular (non-continuity defects): Min: 18 mm Max: 350 mm Mandibular (continuity defects): Min: 25 mm Max: 350 mm	Not applicable	Maxillofacial/ midface: Min: 10 mm Max: 120 mm
Width (Screw-hole dependent)	Maxillofacial/ midface: Min: ≥ 4.5 mm (around screw holes) Min: ≥ 2.5 mm (not around screw hole) Mandibular (non-continuity defects): Min: ≥ 4.5 mm (around screw holes) Min: ≥ 2.5 mm (not around screw hole)	Maxillofacial/ midface: Min: ≥ 4.5 mm (around screw holes) Min: ≥ 2.2 mm (not around screw hole) Mandibular (non-continuity defects): Min: ≥ 4.5 mm (around screw holes) Min: ≥ 2.2 mm (not around screw hole) Mandibular (continuity defects): Min: ≥ 6.4 mm (around screw holes) Min: ≥ 3.2 mm (not around screw hole)	Not applicable	Maxillofacial/ midface: Width: 10 - 100 mm
Overall Thickness	Maxillofacial/ Midface: 1.0 - 1.5 mm Mandibular (non-continuity defects): 1.0 - 2.5 mm	Maxillofacial/Midface: 0.6 - 10 mm Mandibular (non-continuity defects): 0.6 - 10 mm Mandibular (continuity defects): 2.0 - 10 mm.	0.6 mm – 1.0 mm	Maxillofacial/Midface: 0.4 – 0.9 mm
Degree of curvature (In-plane)	Maxillofacial/ midface, Mandibular: Min: 30°	Maxillofacial/ midface, Mandibular: Min: 30°	Not applicable	Maxillofacial/ midface: Min: 45° Max: 180°

	Max: 180°	Max: 180°		
Degree of curvature (Out-of-plane)	Maxillofacial/ midface, Mandibular: Min: 15° Max: 180°	Maxillofacial/ midface, Mandibular: Min: 15° Max: 180°	Not applicable	Not applicable
Hole spacing	Maxillofacial/ midface: ≥4.5 mm Mandibular: ≥4.5 mm (non-continuity defect)	Maxillofacial/ midface: ≥4.5 mm Mandibular: ≥4.5 mm (non-continuity defect) ≥6.4 mm (continuity defect)	Not applicable	Not applicable
Number of holes	Maxillofacial/ midface, Mandibular: ≥2 per side of defect	Maxillofacial/ midface, Mandibular: ≥2 per side of defect	Not applicable	Not applicable
Screw diameter	Maxillofacial /midface: 1.5 - 2.3 mm Mandibular: 2.0 - 2.7 mm	Maxillofacial /midface: 1.5 - 2.3 mm Mandibular: 2.0 - 3.2 mm	1.5 - 2.3 mm	1.5 - 2.3 mm
Screw length	Maxillofacial /midface: 4.0 - 22 mm Mandibular: 5.0 - 22 mm	Maxillofacial /midface: 3.5 - 22 mm Mandibular: 5.0 - 22 mm	4.0 - 19.0 mm	4.0 - 7.0 mm
Screw style	Non-locking	Head style: - maxDrive - crossDrive Design features: - Drill-Free - Locking - ThreadLock TaperScrew - Standard	Head style: - Centre-Drive - maxDrive - crossDrive	Non-locking

7. Performance Tests

Materials and manufacturing method quality of METICULY Patient-specific CMF solution 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 ● ASTM F382-24 Standard Specification and Test Method for Metallic Bone Plates
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 ● ASTM F756-17 (2-250): Standard Practice for Assessment of Hemolytic Properties of Materials ● 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 ● USP-NF M98900_01_01 (2-295): <151> Pyrogen Test (USP Rabbit Test)

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 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 ● ANSI AAMI ST79:2017 (14-562): Comprehensive guide to steam sterilization and sterility assurance in health care facilities ● ISO 11737-1 Third edition 2018-01 (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 ● ISO 14644-1 Second edition 2015-12-15 (14-500) Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration ● ISO 15223-1 Fourth edition 2021-07 (5-134) Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements ● ASTM F1980-16 (14-497) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices ● ASTM F2847-17 Standard Practice for Reporting and Assessment of Residues on Single-Use Implants and Single-Use Sterile Instruments
Table 3: Testing and compliance standards summary table	
Test	**Standard (FDA recognition number)**

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 ● ASTM F1886/F1886M-16 (14-501): Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection ● ASTM 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 CMF solution 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 four comparative tests. According to the results, the METICULY Patient-specific CMF solution 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) and modified compression test	The FEA consideration is based on maximum equivalent stress and safety factors. The modified mechanical test consideration is based on the stiffness and failure observation.	Finite Element Analysis (FEA) computational simulation showed that dimensional or design differences between the subject device and the reference device do not raise new or different questions regarding substantial equivalence.
Comparative mechanical testing	Mechanical testing was performed in accordance with ASTM F382 to compare the bending properties.	The mechanical consideration is based on bending properties described in ASTM F382. The subject device is substantially equivalent to the reference 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.
Table 4: Performance testing summary table		
Test	**Test method summary**	**Results**

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 CMF solution has the same intended use and similar technological characteristics. The device performs as intended and is as safe and effective as the predicate device. Thus, the subject device is concluded to be substantially equivalent to the legally commercialized predicate device for the purposes of this 510(k) submission.