MedCAD
% Justin Gracyalny
Regulatory Affairs Manager
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

9/26/23

Re: K230398
Trade/Device Name: MedCAD® AccuPlate® 3DTi Patient-Specific Plating System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: August 28, 2023
Received: August 28, 2023

Dear Justin Gracyalny:

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)*
K230398

Device Name
MedCAD® AccuPlate® 3DTi Patient-Specific Plating System

Indications for Use *(Describe)*

The MedCAD® AccuPlate® 3DTi Patient-Specific Plating System is intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions in adolescents (greater than 12 to 21 years of age) and adults.

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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K230398

510(k) SUMMARY:

MedCAD® AccuPlate® 3DTi Patient-Specific Plating System

Date Prepared	September 26, 2023
Sponsor Contact	MedCAD 501 S 2nd Ave, Suite A-1000 Dallas, TX 75226 (214) 453-8864
510(k) Contact(s)	Secure BioMed Evaluations Justin Gracyalny, MSE Linda Braddon, Ph.D. 7828 Hickory Flat Highway Suite 120 Woodstock, GA 30188 770-837-2681 Regulatory@SecureBME.com
Trade Name	MedCAD® AccuPlate® 3DTi Patient-Specific Plating System
Code – Classification	Classification Name: Bone Plate (21 CFR 872.4760) Regulatory Class: II Product Code: JEY
Primary Predicate	K191028 KLS Martin Individual Patient Solutions
Reference Devices	K953385 Walter Lorenz Surgical, Inc. Lorenz System K210731 KLS Martin Individual Patient Solutions K203282 Industrias Medicas Sampedro S.A.S. TECHFIT Patient-Specific Maxillofacial System K170272 Materialize N.V. TruMatch CMF Titanium 3D Printed Implant System K192282 MedCAD® AccuPlan® System
Device Description	The MedCAD AccuPlate® 3DTi Patient-Specific Plating System is a metal bone plate used in conjunction with commercially available, non-locking metal bone screws for the fixation to bone in orbital, midface / maxillofacial, and non-continuity mandibular operations. The design and dimensions of each plate within the envelope specification is based upon the patient's anatomical data (CT scan, CBCT scan, or MRI), and the intended anatomy to be fixated as determined from input provided by the surgeon. The subject device is not intended to be bent or modified in surgery. If for any reason the surgeon chooses not to use the subject device in surgery, they may use any of the commercially available plates to complete the surgery. The subject device is additively manufactured from Ti-6AL-4V Extra Low Interstitial (ELI) titanium alloy, provided non-sterile, must be sterilized prior to use, and is intended for single use only. Plates are fastened to bone using commercially available non-locking bone screws with diameters ranging from 1.5mm to 2.7mm and lengths ranging from 3.5mm to 22mm.

Indications for Use Statement	The MedCAD® AccuPlate® 3DTi Patient-Specific Plating System is intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions in adolescents (greater than 12 to 21 years of age) and adults.

Comparison of Technological Characteristics

The MedCAD AccuPlate® 3DTi Patient-Specific Plating System is substantially equivalent to and are as safe and effective as its predicate device (K191028 KLS Martin Individual Patient Solutions). Table 1 compares the subject, predicate, and reference devices.

Similarities to Predicate

The MedCAD® AccuPlate® 3DTi Patient-Specific Plating System has the same intended use and similar technological characteristics as the identified predicate device. The system employs similar fundamental technologies as the identified predicate / reference devices. The principles of operation and technological characteristics are either identical or substantially equivalent to the predicate / reference devices. The system has similar technological characteristics including:

- The subject device and the predicate / reference devices have hole features to accommodate commercially available non-locking fixation screws.
- The subject device uses the same patient specific design software and process flow as the reference device (K192282).
- The subject device design envelope is similar to the predicate / reference devices (K191028, K210731, K203282, K170272).
- The subject device has equivalent mechanical performance to the reference device (K953385).
- Sterility assurance level of $1x10^{-6}$

Differences to Predicate

The following differences exist between the subject and predicate devices:

- The subject and predicate device may both be additively manufactured from Ti-6Al-4V ELI titanium alloy per ASTM F136. However, the primary predicate device may also be subtractively manufactured from commercially pure titanium per ASTM F67. The absence of this design configuration does not raise new concerns for substantial equivalence.
- The subject device is indicated for both adolescents (greater than 12 to 21 years of age) and adults while the patient population in the predicate device is not specified. The use of patient specific facial implants in adolescent populations in identical to that seen in the reference devices (K210731, K170272). As such, this difference does not raise new concerns for substantial equivalence.
- The predicate device includes mandibular plates for treatment of continuity mandibular defects while the subject device is only intended to treat non-continuity mandibular defects. This difference is addressed via a design envelope appropriate for the intended use and labeling. As such, this difference does not raise new concerns for substantial equivalence.

Biocompatibility Testing

Biocompatibility testing was conducted in accordance with international standard ISO 10993-1, ISO10993-5, and FDA guidance document "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'". The results of the testing adequately address biocompatibility for the plates and their intended use.

Sterilization Validation

A sterilization validation was conducted in accordance with international standard ISO 17665-1, ISO 17665-2, and FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" to a sterility Assurance Level (SAL) of 10^{-6}. All test method acceptance criteria were met.

Non-Clinical Performance Testing

Performance testing for the MedCAD® AccuPlate® 3DTi Patient-Specific Plating System is summarized below:

- Static and Dynamic Bending per ASTM F382 – The subject device was shown to have equivalent bending strength and fatigue life as the reference device (K953385).
- Axial Screw Pushout per ASTM F543 – The subject device plate / screw interface was shown to have equivalent axial screw pushout strength as the reference device (K953385).
- Fit and Form Validation – The subject device patient specific design process was shown to produce devices that aligned with the approved surgical plan.

Conclusions

Based on the similarities of the intended use/indications for use, technological and functional characteristic, and the results of the non-clinical performance testing, the subject device is substantially equivalent to the legally marketed predicate device.

Table 1 – Comparison of Technological Characteristics

Trait	Proposed Subject Device MedCAD AccuPlate® 3DTi Patient-Specific Plate	Primary Predicate Device KLS Martin Individual Patient Solutions K191028	Reference Device Walter Lorenz Surgical, Inc. Lorenz System K953385	Reference Device KLS Martin Individual Patient Solutions K210731	Reference Device Industrias Medicas Sampedro S.A.S. TECHFIT Patient-Specific Maxillofacial System K203282	Reference Device Materialize N.V. TruMatch CMF Titanium 3D Printed Implant System K170272
Purpose	Subject Device	Same Indications	Similar Dimensions and Performance	Similar Dimensions and Patient Population	Similar Dimensions (Midface Hole Spacing)	Similar Dimensions (Orbital Plate Thickness)
Product Code	JEY	JEY	JEY	JEY	JEY	JEY
Device Class	Class II	Class II	Class II	Class II	Class II	Class II
Regulation	21 CFR 872.4760	21 CFR 872.4760	21 CFR 872.4760	21 CFR 872.4760	21 CFR 872.4760	21 CFR 872.4760
Indications for Use	The MedCAD® AccuPlate® 3DTi Patient-Specific Plating System is intended for use in the stabilization, fixation, and reconstruction of the maxillofacial / midface and mandibular skeletal regions in adolescents (greater than 12 to 21 years of age) and adults.	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.	These devices are implantable bone plates and bone screws for facial procedures including: 1. Fractures 2. Osteotomies 3. Reconstructive procedures 4. Revision procedures where other treatments or devices have failed	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. 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.	TECHFIT Patient-Specific Maxillofacial System is intended for use in the stabilization, fixation, and reconstruction of the maxillofacial/midface and mandibular skeletal regions.	The TruMatch CMF Titanium 3D Printed Implant System is intended for bone repositioning, fixation and reconstruction of the maxillofacial skeleton, midface, mandible and chin in adolescents (greater than 12 to 21 years of age) and adults. Specific indications for use: • Orthognathic surgery. • Reconstructive mandible and maxillofacial surgery. • Mandible and maxillofacial trauma surgery.
Sterility	Provided non-sterile Steam Sterilized SAL 10^{-6}	Provided non-sterile Steam Sterilized SAL 10^{-6}	Provided non-sterile Steam Sterilized SAL 10^{-6}	Provided non-sterile Steam Sterilized SAL 10^{-6}	Provided non-sterile Steam Sterilized SAL 10^{-6}	Provided non-sterile Steam Sterilized SAL 10^{-6}
Patient Population	Adolescents (12 – 21 years of age) Adults (21+ years of age)	Unknown	Unknown	Children (2 – 12 years of age) Adolescents (12 – 21 years of age) Adults (21+ years of age)	Unknown	Adolescents (12 – 21 years of age) Adults (21+ years of age)

Trait	Proposed Subject Device MedCAD AccuPlate® 3DTi Patient-Specific Plate	Primary Predicate Device KLS Martin Individual Patient Solutions K191028	Reference Device Walter Lorenz Surgical, Inc. Lorenz System K953385	Reference Device KLS Martin Individual Patient Solutions K210731	Reference Device Industrias Medicas Sampedro S.A.S. TECHFIT Patient-Specific Maxillofacial System K203282	Reference Device Materialize N.V. TruMatch CMF Titanium 3D Printed Implant System K170272
Physical Shape	Patient Specific Criteria (manufactured to final geometry)	Patient Specific Criteria (manufactured to final geometry)	Patient Specific Criteria (bent to final geometry during surgery)	Patient Specific Criteria (manufactured to final geometry)	Patient Specific Criteria (manufactured to final geometry)	Patient Specific Criteria (manufactured to final geometry)
Anatomical Locations	• Orbital • Midface / Maxillofacial • Mandible	• Orbital • Midface / Maxillofacial • Mandible	• Orbital • Midface / Maxillofacial • Mandible	• Orbital • Midface / Maxillofacial • Mandible	• Midface / Maxillofacial • Mandible	• Orbital • Midface / Maxillofacial • Mandible
Material	Ti-6AL-4V Extra Low Interstitial (ELI) Titanium Alloy (Grade 23) per ASTM F136	Surgical Guides: Epoxy/Acrylic Resins Implants: Commercially Pure Titanium per ASTM F67 or Ti-6AL-4V ELI per ASTM F136Commercially Pure Titanium per ASTM F67	Commercially Pure Titanium per ASTM F67	Surgical Guides: Epoxy/Acrylic Resins Implants: Commercially Pure Titanium per ASTM F67 or Ti-6AL-4V ELI per ASTM F136	Commercially Pure Titanium per ASTM F67	Commercially Pure Titanium per ASTM F67
Manufacturing Method	3D Printed (Additive Manufacturing)	Traditional (Subtractive) 3D Printed (Additive Manufacturing)	Traditional (Subtractive)	Traditional (Subtractive) 3D Printed (Additive Manufacturing)	Traditional (Subtractive)	3D Printed (Additive Manufacturing
Plate Thickness	Orbital: 0.6mm – 1.2mm Maxillofacial / Midface: 0.8mm – 2.0mm Mandibular (Non-Continuity Defects): 0.8mm – 2.0mm	Orbital: 0.3mm – 1.0mm Maxillofacial / Midface: 0.6mm – 10mm Mandibular Reconstruction: 1.0mm – 3.0mm	0.2mm – 2.6mm	Orbital: 0.3mm – 1.0mm Maxillofacial / Midface: 0.6mm – 10mm Mandibular (Non-Continuity Defects): 0.6mm – 10mm Mandibular (Continuity Defects): 2.0mm – 10mm	Maxillofacial / Midface : 0.6 mm – 2.0 mm Mandibular: 2.0 mm – 3.0 mm	Orbital: 0.8mm – 1.2mm Maxillofacial / Midface: 0.8mm – 3.0mm Mandibular: 0.8mm – 3.0mm

Trait	Proposed Subject Device MedCAD AccuPlate® 3DTi Patient-Specific Plate	Primary Predicate Device KLS Martin Individual Patient Solutions K191028	Reference Device Walter Lorenz Surgical, Inc. Lorenz System K953385	Reference Device KLS Martin Individual Patient Solutions K210731	Reference Device Industrias Medicas Sampedro S.A.S. TECHFIT Patient-Specific Maxillofacial System K203282	Reference Device Materialize N.V. TruMatch CMF Titanium 3D Printed Implant System K170272
Plate Width	Orbital: Min: ≥ 3.9 mm (around screw holes) Min: ≥ 2.5 mm (not around screw hole) Maxillofacial / Midface: Min: ≥ 4.5 mm (around screw holes) Min: ≥ 2.5 mm (not around screw hole) Mandibular (Non-Continuity Defect): 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: ⩾ 3 mm (not around screw hole) Max: Dependent on screw-hole Mandibular: Min: 7 mm Min: 8.5mm	Unknown	Orbital: Min: ≥ 3.5 mm (around screw holes) Min: ≥ 2.2 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 Defect): Min: ≥ 4.5 mm (around screw holes) Min: ≥ 2.2 mm (not around screw hole) Mandibular (Continuity Defect): Min: ≥ 6.4 mm (around screw holes) Min: ≥ 3.2 mm (not around screw hole)	Maxillofacial / Midface: Min: ≥ 4.5 mm (around screw holes) Min: ≥ 3 mm (not around screw hole) Mandibular: Min: 6.63 mm Max: 16 mm	Orbital: 0.6mm – 1.2mm Maxillofacial / Midface: 0.8mm – 2.0mm Mandibular (Non-Continuity Defects): 0.8mm – 2.0mm
Number of Holes	Orbital, Mandibular, Maxillofacial / Midface: Min: ≥2 per side of defect Max: Dependent on length & hole spacing	Orbital & Maxillofacial / Midface: Min: ⩾ 2 per side of defect Max: Dependent on length & hole spacing Mandibular: Min: 4 Max: Dependent on length & hole spacing	Unknown	Orbital, Mandibular, Maxillofacial / Midface: ≥ 2 per side of defect	Maxillofacial/midface: Min: ≥ 2 per side of defect Max: Dependent on length & hole spacing Mandibular: Min: 4 Max: Dependent on length & hole spacing	Unknown
Hole Spacing	Orbital: ≥4.0mm Maxillofacial / Midface: ≥4.0mm Mandibular (Non-Continuity Defects): ≥4.5mm	Orbital & Maxillofacial / Midface: ⩾4.5mm Mandibular: ⩾8.0mm	Unknown	Orbital: ≥3.5mm Maxillofacial / Midface: ≥4.5mm Mandibular (Non-Continuity Defects): ≥4.5mm Mandibular (Continuity Defects): ≥6.4mm	Maxillofacial: ≥ 4.5 mm Midface: ≥ 4.0 mm Mandibular: ≥ 8 mm	Unknown

Trait	Proposed Subject Device MedCAD AccuPlate® 3DTi Patient-Specific Plate	Primary Predicate Device KLS Martin Individual Patient Solutions K191028	Reference Device Walter Lorenz Surgical, Inc. Lorenz System K953385	Reference Device KLS Martin Individual Patient Solutions K210731	Reference Device Industrias Medicas Sampedro S.A.S. TECHFIT Patient-Specific Maxillofacial System K203282	Reference Device Materialize N.V. TruMatch CMF Titanium 3D Printed Implant System K170272
Plate Length	Orbital: 16mm – 50m Maxillofacial / Midface: 18mm – 350mm Mandibular (Non-Continuity Defects): 18mm – 350mm	Orbital & Maxillofacial / Midface: 18 – 350mm Mandibular: 31 – 320mm	Unknown	Orbital: 10.5mm – 50m Maxillofacial / Midface: 18mm – 350mm Mandibular (Non-Continuity Defects): 18mm – 350mm Mandibular (Continuity Defects): 25mm – 350mm	Maxillofacial / Midface: 18mm – 350mm Mandibular: 78mm – 320mm	Orthognathic: 20mm maximum advancement Orbital: 5.5mm – 45mm Maxillofacial / Midface / Mandibular: 20 mm maximum bridging of osteotomy gap; Small: 20-120mm, Large: 20-294mm
Plate Holes	No locking threads	Locking threads optional	Locking threads optional	Locking threads optional	Unknown	Unknown
Degree of Curvature	Orbital: In Plane: 30° - 180° Out of Plane: 15° - 180° Maxillofacial / Midface: In Plane: 30° - 180° Out of Plane: 15° - 180° Mandibular (Non-Continuity Defects): In Plane: 30° - 180° Out of Plane: 15° - 180°	Maxillofacial / Midface: In Plane: 30° - 180° Out of Plane: 15° - 180° Mandibular: In Plane: 90° - 180° Out of Plane: 60° - 180°	Unknown	Orbital: In Plane: 30° - 180° Out of Plane: 15° - 180° Maxillofacial / Midface: In Plane: 30° - 180° Out of Plane: 15° - 180° Mandibular (Non-Continuity Defects): In Plane: 30° - 180° Out of Plane: 15° - 180° Mandibular (Continuity Defects): In Plane: 30° - 180° Out of Plane: 15° - 180°	Maxillofacial / Midface: In Plane: 30° - 180° Out of Plane: 15° - 180° Mandibular: In Plane: 90° - 180° Out of Plane: 60° - 180°	Orthognathic: 0° - 119° Orbital: 12°/mm length Maxillofacial / Midface: 12°/mm length Mandibular: 12°/mm length
Compatible Screw Diameter	Orbital: 1.5mm Maxillofacial / Midface: 1.5mm – 2.3mm Mandibular: 2.0mm – 2.7mm	Orbital: 1.5mm Maxillofacial / Midface: 1.5mm – 2.3mm Mandibular: 2.0mm – 3.2mm	1.5mm – 2.7mm	Orbital: 1.5mm Maxillofacial / Midface: 1.5mm – 2.3mm Mandibular: 2.0mm – 3.2mm	Unknown	Unknown
Compatible Screw Length	Orbital: 3.5mm – 22mm Maxillofacial / Midface: 3.5mm – 22mm Mandibular: 3.5mm – 22mm	Orbital: 3.5mm – 22mm Maxillofacial / Midface: 3.5mm – 22mm Mandibular: 5mm – 22mm	3.5mm – 18mm	Orbital: 3.5mm – 22mm Maxillofacial / Midface: 3.5mm – 22mm Mandibular: 5mm – 22mm	Unknown	Unknown