February 12, 2021

MedCAD
% Linda Braddon
President/CEO
Secure BioMed Evaluations
7828 Hickory Flat Highway Suite 120
Woodstock, Georgia 30188

Re: K193280
Trade/Device Name: MedCAD® AccuPlate® Patient-Specific Plate
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY
Dated: January 11, 2021
Received: January 12, 2021

Dear Linda Braddon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Andrew Steen
Assistant Director
DHT1B: Division of Dental 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)*

K193280

Device Name

MedCAD® AccuPlate® Patient-Specific Plate

Indications for Use *(Describe)*

The MedCAD® AccuPlate® Patient-Specific Plate is intended for prescription use in oral and maxillofacial surgery, trauma and reconstructive surgery.

Specific Indications for Use:

- Primary mandibular reconstruction with bone graft
- Temporary bridging until delayed secondary reconstruction
- Secondary mandibular reconstruction
- Comminuted mandibular fractures
- Fractures of edentulous and/or atrophic mandibles
- Unstable mandibular fractures
- Maxillary reconstruction with or without bone graft
- Maxillary trauma

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
MedCAD® AccuPlate® Patient-Specific Plates K193280

February 10, 2021

Sponsor

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Contact

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Name of Device and Classification Name

Device Name: MedCAD® AccuPlate® Patient-Specific Plate
Regulation Name: Bone Plate
Regulation Number: 872.4760
Product Code: Primary – JEY
Classification Panel: Dental

Predicate Device

Synthes Patient-Specific Plates (K122647)

Reference Devices

Stryker Customized Mandible Recon Plate Kit (K132519)
Biomet Fracture/Reconstruction System Trauma One (K081067)
MedCAD AccuShape™ PEEK Specific Cranial Implant (PSCI) (K110684)

Indication for Use:

The MedCAD® AccuPlate® Patient-Specific Plate is intended for prescription use in oral and maxillofacial surgery, trauma and reconstructive surgery.

Specific Indications for Use:

- Primary mandibular reconstruction with bone graft
- Temporary bridging until delayed secondary reconstruction
- Secondary mandibular reconstruction
- Comminuted mandibular fractures

- Fractures of edentulous and/or atrophic mandibles
- Unstable mandibular fractures
- Maxillary reconstruction with or without bone graft
- Maxillary trauma

Device Description

MedCAD® AccuPlate® Patient-Specific Plates are metal bone plates used in conjunction with commercially available metal bone screws for the fixation to bone, specifically in the areas of the mandible and maxilla. 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 plates are designed by MedCAD in consultation with the surgeon and manufactured by MedCAD only. MedCAD® AccuPlate® Patient-Specific Plates are not intended to be bent or modified in surgery. The MedCAD® AccuPlate® Patient-Specific Plates are manufactured from commercially pure titanium, are provided non-sterile, must be sterilized prior to use, and are intended for single use only. Plates are fastened to bone using commercially available bone screws with diameters ranging from 2.0 mm to 2.7 mm and lengths ranging from 4.0 mm to 23.0 mm.

Performance Data

Non-clinical testing was performed to demonstrate the MedCAD® AccuPlate® Patient-Specific Plates are substantially equivalent to other predicate / reference devices. The following comparative tests were performed:

• Static and dynamic 4 point bending per ASTM F382
• Screw pushout testing

The results of these studies show the subject MedCAD® AccuPlate® Patient-Specific Plates meets the performance of the predicate / reference devices, and the device was therefore found to be substantially equivalent.

Sterilization Validation

Sterilization validation was conducted in accordance with international standard ISO 17665-1 and FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." to a sterility Assurance Level (SAL) of $1x10^{-6}$. All test method acceptance criteria were met.

Biocompatibility Validation

Biocompatibility validation was conducted in accordance with international standard ISO 10993-1 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.

Based on risk management , the following biocompatibility testing was conducted on the final, finished sterilized device:

- Cytotoxicity per ISO 10993-5
- Scanning Electron Microscope (SEM) imaging and Energy Dispersive X-Ray Spectroscopy (EDS) analysis for evaluation of the elemental analysis of the surface of the bone plate

Substantial Equivalence

MedCAD® AccuPlate® Patient-Specific Plates are substantially equivalent to the identified predicate based on indications for use, principles of operation, material composition, and technological characteristics.

COMPARISON OF TECHNOLOGICAL CHARACTERISITICS				
Features	**Subject Device MedCAD® AccuPlate® Patient-Specific Plate (K193280)**	**Predicate Device Synthes Patient Specific Plates (K122647)**	**Reference Device Stryker Customized Mandible Recon Plate Kit (K132519)**	**Reference Device Biomet Fracture/Reconstruction System (Traumaone) (K081067)**
Indications for Use	The MedCAD® AccuPlate® Patient-Specific Plate is intended for prescription use in oral and maxillofacial surgery, trauma and reconstructive surgery. Specific Indications for Use: • Primary mandibular reconstruction with bone graft • Temporary bridging until delayed secondary reconstruction • Secondary mandibular reconstruction • Comminuted mandibular fractures • Fractures of edentulous and/or atrophic mandibles • Unstable mandibular fractures • Maxillary reconstruction with or without bone graft • Maxillary trauma	Synthes Patient Specific Plates are intended for use in oral and maxillofacial surgery, trauma and reconstructive surgery. Specific Indications for Use: • Primary mandibular reconstruction with bone graft • Temporary bridging until delayed secondary reconstruction • Secondary mandibular reconstruction • Comminuted mandibular fractures • Fractures of edentulous and/or atrophic mandibles • Unstable mandibular fractures • Maxillary reconstruction with or without bone graft • Maxillary trauma	The Customized Mandible Recon Plate Kit is indicated for use in primary mandibular reconstruction with bone graft, temporary bridging until delayed secondary reconstruction and secondary mandibular reconstruction.	Intended for use in the stabilization and fixation of mandibular fractures and mandibular reconstructive surgical procedures.
Material	Commercially Pure Titanium	Commercially Pure Titanium	Commercially Pure Titanium	Commercially Pure Titanium
Manufacturing Method	Subtractive	Subtractive	Subtractive	Subtractive
Sterility	Provided non-sterile	Provided non-sterile	Provided non-sterile	Provided non-sterile

COMPARISON OF TECHNOLOGICAL CHARACTERISITICS				
Features	**Subject Device MedCAD® AccuPlate® Patient-Specific Plate (K193280)**	**Predicate Device Synthes Patient Specific Plates (K122647)**	**Reference Device Stryker Customized Mandible Recon Plate Kit (K132519)**	**Reference Device Biomet Fracture/Reconstruction System (Traumaone) (K081067)**
Physical Shape	Patient Specific Criteria	Patient Specific Criteria	Patient Specific Criteria	Generic Template that is bent to patient specific criteria.
Visual Appearance	Opaque	Opaque	Opaque	Opaque
Plate Thickness	2.0 mm and 2.8 mm	2.0 mm and 2.5 mm	2.0 mm and 2.8 mm	2.0 mm, 2.6 mm, 2.8 mm
Plate Height	8.25 mm Minimum	8.0 mm	6.5 mm / 7.6 mm	6.98 mm / 8.25 mm / 8.25 mm
Hole Spacing (minimum)	7.5 mm for 2.0 mm Plate 9.0 mm for 2.8 mm Plate	5.5 mm	7.6 mm for 2.0 mm Plate 9.0 mm for 2.8 mm Plate	7.5 mm
Plate Length Max length defined by patient anatomy	30 mm – 490 mm	24.5 mm – 490 mm	*Not publicly disclosed*	30 mm – 251 mm
Plate Holes	Locking Threads Optional	Locking Threads Optional	Locking Threads Optional	Locking Threads Optional
Hole Angulation	0°	0-15°	0-10°	0-15°
Screw Diameter	2.0 mm, 2.3 mm, 2.4 mm, 2.7 mm	2.4 mm or 2.9 mm	*Not publicly disclosed.*	2.0 mm, 2.3 mm, 2.7 mm
Shape Design	Mandible Hemi (L or R) Mandible Angle to Angle, Mandible Condyle to Condyle, Maxilla	"During the plate design process, surgeons will select the options for the plate design, which may include the following: Choose plate profile, Define plate trajectory"	"Full" or "Hemi"	Full Mandible (angle to angle), Left & Right Hemi-mandible (angle to symphysis of chin), Straight Plate (no angle)
Range of lengths for each shape design or model type	30 mm – 490 mm	24.5 mm – 490 mm	"Plate design is based upon a CT scan of the patient. Selecting specific plate design features like profile height, length, and run of the plate allow for the creation of patient specific solutions"	30 mm – 251 mm
Maximum dimensions for each shape design or model type	Thickness: 2.0 mm and 2.8 mm Length: 30 mm – 490 mm	Thickness: 2.0 mm – 2.5 mm Length: 24.5 mm – 490 mm	Thickness: 2.0 mm and 2.8 mm Length: *Not publicly disclosed*	Thickness: 2.0 mm, 2.6 mm, 2.8 mm Length: 30 mm – 251 mm

Comparison of Technological Characteristics with the Predicate Device

MedCAD® AccuPlate® Patient-Specific Plates are substantially equivalent to its predicate device (Synthes Patient Specific Plates - K122647).

Similarities to Predicate

The MedCAD® AccuPlate® Patient-Specific Plates 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 principals of operation and technological characteristics are either identical or substantially equivalent to the predicate / reference devices. The system has similar technological characteristics including:

- Materials: Commercially pure titanium (proposed device and the reference (K081067) are manufactured from Grade 2 commercially pure titanium).
- Plate thickness: The proposed device is offered in nominal thickness of 2.0 mm and 2.8 mm. The thickness of the predicate / reference devices range from 2.0 mm to 2.8 mm.
- Technical Characteristics: The proposed device and predicate / reference devices share similar technical characteristics including available lengths, thicknesses, heights, curvatures, hole spacing, and material. The proposed device and the predicate / reference devices have hole features that are geometrically the same to accommodate commercially available fixation screws.
- The proposed device and the reference (K110684) share the same fundamental principles of processing the patient data (i.e. CT Scan) for use as input.
- The proposed device and the predicate / references are manufactured similarly via CNC milling.
- Sterility assurance level of $1x10^{-6}$

Differences to Predicate

The following differences exist between the subject and predicate / reference devices:

- The proposed subject device is manufactured to the planned patient anatomy whereas the reference device(s) (Biomet and Stryker) are first manufactured flat, and then bent to match patient anatomy. This manufacturing difference does not create a new risk since the end product of both processes are designed to fit the patient and the performance testing is equivalent.
- The proposed subject device is Grade 2 commercially pure titanium while the predicate device (K122647) utilize Grades 1,2,3,4, and 5 titanium. The differences in material do not create a risk for biocompatibility or mechanical performance.

Conclusion

Based on the indications for use, technological characteristics, performance testing, and comparison to predicate / reference devices, the subject MedCAD® AccuPlate® Patient-Specific Plates have been shown to be substantially equivalent to the predicate devices.