March 7, 2023

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

Re: K223024
Trade/Device Name: MedCAD® AccuPlan® System
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone cutting instrument and accessories
Regulatory Class: Class II
Product Code: DZJ, LLZ
Dated: February 6, 2023
Received: February 7, 2023

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE.
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)*
K223024

Device Name
MedCAD® AccuPlan® System

Indications for Use *(Describe)*

The MedCAD® AccuPlan® System is intended for use as a software system 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 MedCAD® AccuPlan® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, surgical guides, and dental splints for use in maxillofacial surgery. The surgical guides and dental splints are intended to be used for the maxillofacial bone in maxillofacial surgery. The MedCAD® AccuPlan® System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

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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K223024
510(k) Summary
MedCAD® AccuPlan® System

March 7, 2023

Sponsor
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Name of Device and Classification Name
Device Name: MedCAD® AccuPlan® System
Regulation Name: Bone Cutting Instruments and Accessories
Regulation Number: 872.4120
Product Code: Primary – DZJ; Secondary – LLZ
Classification Panel: Dental

Predicate Device(s)
MedCAD® AccuPlan® System (K192282)

Reference Device(s)
KLS Martin Individual Patient Solutions (IPS) Planning System (K181241)
MedCAD® AccuShape® Titanium Patient-Specific Cranial Plate (K220357)

Indication for Use:
The MedCAD® AccuPlan® System is intended for use as a software system 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 MedCAD® AccuPlan® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, surgical guides, and dental splints for use in maxillofacial surgery. The surgical guides and dental splints are intended to be used for the maxillofacial bone in maxillofacial surgery. The MedCAD® AccuPlan® System is also intended as a pre-operative software tool for simulating /evaluating surgical treatment options.

Device Description

The MedCAD® AccuPlan® System is a collection of software and associated additive manufacturing equipment intended to provide a variety of outputs to support orthognathic or reconstructive surgery. The system uses electronic medical images of the patient's anatomy or stone castings made from the patient anatomy with input from the physician, to manipulate original patient images for planning and executing surgery. The patient specific outputs from the system includes anatomical models, dental splints, surgical guides, and patient-specific case reports.

Following the MedCAD® Quality System and specific Work Instructions, trained employees utilize Commercial Off-The-Shelf (COTS) software to manipulate 3-D medical scan images which can include Computed Tomography (CT), Cone Beam CT (CBCT), and/or 3-D scan images from patient physical models (stone models of the patient's teeth) to create patient-specific physical and digital outputs. The process requires clinical input and review from the physician during planning and prior to delivery of the final outputs. While the process and dataflow vary somewhat based on the requirements of a given patient and physician, the following description outlines the functions of key sub-components of the system, and how they interact to produce the defined system outputs. It should be noted that the system is operated only by trained MedCAD employees, and the physician does not directly input information. The physician provides input for model manipulation and interactive feedback through viewing of digital models of system outputs that are modified by the engineer during the planning session.

The MedCAD® AccuPlan® System is made up of 4 individual pieces of software for the design and various manufacturing equipment integrated to provide a range of anatomical models (physical and digital), dental splints, surgical guides, and patient-specific planning reports for reconstructive surgery in the maxillofacial region.

The MedCAD® AccuPlan® System requires an input 3-D image file from medical imaging systems (i.e. - CT) and/or implant file. This input is then used, with support from the prescribing physician to provide the following potential outputs to support reconstructive surgery. Each system output is designed with physician input and reviewed by the physician prior to finalization. All outputs are used only with direct physician involvement to reduce the criticality of the outputs.

System outputs include:

- Anatomical Models
- Surgical Guides
- Dental Splints
- Patient-Specific Case Reports

The purpose of this submission was to add titanium cutting / drilling guides to the family of available patient specific outputs. Cutting and drilling instruments can only be used with titanium cutting / drilling guides. Polymer guides are to be used for marking and positioning of anatomy only.

Sterilization Validation

Sterilization validation was conducted in accordance with international standard ISO 17665 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 output devices and their intended use.

Performance Testing

Performance testing for the MedCAD® AccuPlan® System is summarized in the table below:

Test	Test Method Summary	Results
Wear Debris Testing	Cutting / drilling instruments were used on a worst-case titanium surgical guide. The quantity of wear debris generation was characterized.	**PASS** The wear debris generated by the subject device is less than that reported in the literature to be safe.
Fit and Form Validation	Subject devices from historical cases were manufactured. The manufactured devices were optically scanned to verify alignment with the 3D model. Evaluation of fit was also validated by fitting the guide over the corresponding defect in a representative anatomical model.	**PASS** All samples met the predetermined acceptance criteria.

Substantial Equivalence

MedCAD® AccuPlan® System is substantially equivalent to the identified predicate based on indications for use, principles of operation, technological characteristics, inputs, and outputs. Minor differences in the surgical planning and manufacturing processes are verified and validated in the performance data in accordance with the intended use.

The input is images from medical scanners, dental models, and/or implants files. Physical outputs include dental splints and surgical guides. Biocompatible materials are used in the creation of the subject devices.

All devices are intended to aid in maxillofacial surgeries. These systems are intended to be utilized by trained employees with the approval by the physician.

COMPARISON OF TECHNOLOGICAL CHARACTERISITICS		
	MedCAD® AccuPlan® System	**MedCAD® AccuPlan® System**
510(k) Number	K223024	K192282
Indications for Use	The MedCAD® AccuPlan® System is intended for use as a software system 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 MedCAD® AccuPlan® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, surgical guides, and dental splints for use in maxillofacial surgery. The surgical guides and dental splints are intended to be used for the maxillofacial bone in maxillofacial surgery. The MedCAD® AccuPlan® System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.	The MedCAD® AccuPlan® System is intended for use as a software system 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 MedCAD® AccuPlan® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, surgical guides, and dental splints for use in maxillofacial surgery. The surgical guides and dental splints are intended to be used for the maxillofacial bone in maxillofacial surgery. The MedCAD® AccuPlan® System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.
Preoperative software	Yes	Yes
Additive manufacturing of splints, guides, and models	Yes	Yes
Data inputs	Images from medical scanners	Images from medical scanners
Data outputs	Output for dental splints, surgical guides, and anatomical models	Output for dental splints, surgical guides, and anatomical models
Physical outputs	Dental splints, surgical guides, anatomical models, and patient-specific case reports	Dental splints, surgical guides, anatomical models, and patient-specific case reports
Materials	Biocompatible polymers and Ti-6Al-4V ELI Titanium Alloy per ASTM F136	Biocompatible polymers
Sterilization	Provided non-sterile and is steam sterilized by the end-user	Provided non-sterile and is steam sterilized by the end-user
Manufacturing Method	Additive Manufacturing	Additive Manufacturing
Patient Contact	Surgical Guides: Implant – Tissue / Bone; Limited (< 24 hours) Splint – Intermediate: Surface Contacting – Mucosal Membrane; Limited (< 24 hours) Splint – Final: Externally Communicating – Tissue / Bone / Dentin; Limited (< 24 hours)	Surgical Guides: Implant – Tissue / Bone; Limited (< 24 hours) Splint – Intermediate: Surface Contacting – Mucosal Membrane; Limited (< 24 hours) Splint – Final: Externally Communicating – Tissue / Bone / Dentin; Limited (< 24 hours)

Comparison of Technological Characteristics with the Predicate Device

MedCAD® AccuPlan® system is substantially equivalent to and it is safe and effective as its predicate device (MedCAD® AccuPlan® system – K192282).

Similarities to Predicate

The subject device is identical to that cleared in K192282 with the exception that the subject device also includes titanium cutting and drilling surgical guides. The anatomical models, splints, and marking and positioning surgical guides are identical to those cleared in K192282.

The MedCAD® AccuPlan® System has the same intended use and similar technological characteristics as the identified predicate device. The system employs similar fundamental technologies as the identified predicates including software image transfer, manipulation, and surgical planning. The principals of operation and technological characteristics are either identical or substantially equivalent to the predicate. The system has similar technological characteristics including:

- System inputs: Images from medical scanners (ex: CT), dental models, and/or implant files (.STL)
- System outputs: Physical and/ or Digital outputs such as patient-specific anatomical models, marking and positioning guides, and splints
- Materials: Biocompatible polymers and Ti-6Al-4V ELI Titanium Alloy per ASTM F136
- Sterility assurance level of $1x10^{-6}$

The intended use of the subject device and the predicate both provide tools and accessories (software for image manipulation, anatomical models, splints, and guides) for use in reconstructive surgery. Additionally, both the subject and the predicate device are intended to be used by trained personnel with active support from the surgeon.

Differences to Predicate

The subject device is identical to that cleared in K192282 with the exception that the subject device also includes titanium cutting and drilling surgical guides. The inclusion of these components within the subject device system is similar to those cleared in the reference device (K181241). Safety and performance testing demonstrate that the addition of these components does not raise new questions for substantial equivalence.

Conclusion

The MedCAD® AccuPlan® System is substantially equivalent to its predicate device.