October 29, 2020

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

Re: K192282
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: October 2, 2020
Received: October 2, 2020

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 Srinivas “Nandu” Nandkumar, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192282

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW. ***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human
Services Food and Drug Administration
Office of Chief Information
Officer Paperwork Reduction
Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
MedCAD® AccuPlan® System K192282

October 29, 2020

Sponsor
MedCAD
501 S 2nd Ave, Suite A-1000
Dallas, TX 75226
(214) 453-8864 x305

Contact
Secure BioMed Evaluations
Linda Braddon, Ph.D.
7828 Hickory Flat Highway
Suite 120
Woodstock, GA 30188
770-837-2681
Regulatory@SecureBME.com

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
VSP® System, Medical Modeling, Inc. (K120956)

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, surgical guides, dental splints, 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 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 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

Performance Data

The performance data indicates that the verification and validation testing performed on the MedCAD® AccuPlan® system successfully demonstrates that design outputs meet design inputs.

Device Performance Validation

The performance testing for the device includes processes validation methods such as IQ, OQ, and PQ to ensure that the manufacturing process can effectively produce patient matched devices. Equipment used for production purposes have been qualified to ensure the equipment used for manufacturing of surgical guides, dental splints, and anatomical models meet production needs. Dental splints and surgical guides are manufactured based on

recommendations outlined in the FDA Guidance Document “Technical Considerations for Additive Manufactured Medical Devices.”

Additionally, a dimensional analysis was performed to ensure the proper fit of the final output. Mechanical performance evaluations assessing dynamic compressive strength and ligature wire pullout testing were conducted on final, finished devices demonstrating they are equivalent to the predicate device.

Software System Validation

In order to ensure the off-the-shelf software packages are operating correctly and any necessary file conversions will not negatively impact the final output, software verification and validation activities include:

- Verification of each independent software subsystem against defined requirements
- Verification of compatibility between software subsystems against defined requirements
- Validation of fully integrated system including all subsystems against overall system requirements

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.

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	**VSP® System Medical Modeling Inc.**
510(k) number	K182282	K120956
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 Medical Modeling VSP® 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 VSP® 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, templates, and surgical guides for use in maxillofacial surgery. The VSP® 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 anatomical models, templates, and surgical guides
Physical outputs	Dental splints, surgical guide, anatomical models, and patient-specific case reports	Templates, surgical guides, and anatomical models
Materials	Biocompatible polymers	Biocompatible polymers
Sterilization	Subject device is provided non-sterile and is steam sterilized by the end-user	Predicate device is provided non-sterile and is steam sterilized by the end-user
Manufacturing Method	Additive Manufacturing	Additive Manufacturing
Patient Contact	Guides: Surface Contacting – Tissue / Bone / Mucosal Membrane Limited (< 24 hours) Splints: Surface Contacting – Mucosal Membrane Limited (< 24 hours)	Limited (< 24 hours) Prolonged (< 30 days) Surface Contacting - Mucosal

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 (VSP® System, Medical Modeling, Inc. – K120956).

Similarities to Predicate

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, guides, and splints
- Materials: Biocompatible polymers
- 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 following differences exist between the subject and predicate device:

- The predicate specifically refers to support of reconstructive surgery. The subject device will support both orthognathic (correction of jaw conditions) and reconstructive surgeries.
- The predicate device contains a set of stainless-steel cutting and drill inserts which are intended to be used by the physician to guide cutting and drilling activities during the surgical procedure. The subject device is intended to be used only for positioning and marking as determined by the physician. There is no use of stainless-steel cutting and drill inserts with the subject device.
- The predicate system includes the use of surgical guides for graft bone harvesting which can include the fibula and hip. The subject device is not intended to be used for bone harvesting and is to be used only in the maxillofacial region of the body.
- The Indications for Use statements differ slightly in that the predicate device lists the physical outputs to include “anatomical models, templates, and surgical guides” whereas the subject device includes “anatomical models, surgical guides, and dental splints”. Additionally, the subject device contains the statement “The surgical guides and dental splints are intended to be used for the maxillofacial bone in maxillofacial surgery.”

Conclusion

MedCAD® AccuPlan® is substantially equivalent to and is as safe and effective as its predicate device. Both devices incorporate similar inputs, operations, and outputs.