September 20, 2023

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

Re: K223421
Trade/Device Name: MedCAD® AccuPlan® Orthopedics System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PBF, LLZ
Dated: August 18, 2023
Received: August 18, 2023

Dear Mr. 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 (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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K223421

Device Name
MedCAD® AccuPlan® Orthopedics System

Indications for Use *(Describe)*

MedCAD® AccuPlan® Orthopedics 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 system and the result is an output data file. This file 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 of the fibula and ilium, surgical guides for harvesting bone grafts from the fibula or ilium, and surgical planning case reports for use in maxillofacial reconstructive surgeries. MedCAD® AccuPlan® Orthopedics System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options. The MedCAD® AccuPlan® Orthopedics System is indicated for use 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.**

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

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**K223421**
**510(k) Summary**
**MedCAD® AccuPlan® Orthopedics System**

**September 18, 2023**

**Sponsor**
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(214) 453-8864 x305

**Contacts**
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**Name of Device and Classification Name**
Device Name: MedCAD® AccuPlan® Orthopedics System
Common Device: Orthopaedic Surgical Planning And Instrument Guide
Regulation Name and Number: 21 CFR 888.3030 Single/multiple component metallic bone fixation appliances and accessories, 21 CFR 892.2050 Medical image management and processing system
Product Code: PBF, LLZ
Classification Panel: Orthopedic

**Predicate Device**
CenterMed Patient Matched Assisted Surgical Planning (ASP) System (K211614)

**Reference Devices**
MedCAD® AccuPlan® System (K192282 / K223024)

**Indications for Use:**
MedCAD® AccuPlan® Orthopedics 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 system and the result is an output data file. This file 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 of the fibula and ilium, surgical guides for harvesting bone grafts from the fibula or ilium, and surgical planning case reports for use in maxillofacial reconstructive surgeries. MedCAD® AccuPlan® Orthopedics System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options. The MedCAD® AccuPlan® Orthopedics System is indicated for use in adolescents (greater than 12 to 21 years of age) and adults.

## Device Description

The MedCAD® AccuPlan® Orthopedics System is a collection of software and associated additive manufacturing equipment intended to provide a variety of outputs to support harvesting of bone to support maxillofacial reconstructive surgeries. The system uses electronic medical images of the patient's anatomy with input from the physician to manipulate original patient images for planning and executing surgery. The patient specific outputs from the system include anatomical models, 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 Computed Tomography (CT) images 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® Orthopedics System is made up of two individual pieces of software for the design and various manufacturing equipment integrated to provide a range of anatomical models (physical and digital), surgical guides, and patient-specific planning reports for harvesting of bone from the fibula and ilium for use in maxillofacial reconstructive surgeries.

The MedCAD® AccuPlan® Orthopedics System requires an input 3-D image file from medical imaging systems (i.e., CT). This input is then used, with support from the prescribing physician to provide the following potential outputs to support maxillofacial 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
- Patient-Specific Case Reports

## 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® Orthopedics 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. Wear particles were characterized per ASTM F1877-16. | **PASS**<br><br>The quantity and morphology of wear debris generated by the subject device under worst case use conditions aligns with values as reported in the literature to be safe. |
| Fit and Form Validation | Subject devices were manufactured from worst-case CT scan input data. 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**<br><br>All samples met the predetermined acceptance criteria. |

**Substantial Equivalence**

MedCAD® AccuPlan® Orthopedics System is substantially equivalent to the identified predicate based on indications for use, principles of operation, technological characteristics, inputs, and outputs.

| Property | MedCAD® AccuPlan® Orthopedics System | CenterMed Patient Matched Assisted Surgical Planning (ASP) System |
|---|---|---|
| 510(k) number | K223421 | K211614 |
| Indications for Use | MedCAD® AccuPlan® Orthopedics 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 system and the result is an output data file. This file 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 of the fibula and ilium, surgical guides for harvesting | CenterMed Patient Matched Assisted Surgical Planning (ASP) 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 ASP system and the result is an output data file. This file 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 of the Fibula and Ilium, surgical guides for harvesting |

| Property | MedCAD® AccuPlan® Orthopedics System | CenterMed Patient Matched Assisted Surgical Planning (ASP) System |
|---|---|---|
| | bone grafts from the fibula or ilium, and surgical planning case reports for use in maxillofacial reconstructive surgeries. MedCAD® AccuPlan® Orthopedics System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options. The MedCAD® AccuPlan® Orthopedics System is indicated for use in adolescents (greater than 12 to 21 years of age) and adults. | bone grafts from the Fibula or Ilium, and surgical planning case reports for use in Maxillofacial reconstructive surgeries. CenterMed Patient Matched ASP System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options. |
| Preoperative software | Yes | Yes |
| Additive manufacturing of surgical guides and models | Yes | Yes |
| Data inputs | Images from medical scanners | Images from medical scanners |
| Data outputs | Output for patient-specific surgical guides and anatomical models | Output for patient-specific surgical guides and anatomical models |
| Physical outputs | Patient-specific surgical guides, anatomical models, and patient-specific case reports | Patient-specific surgical guides, anatomical models, and patient-specific case reports |
| Materials | Biocompatible polymers and Ti-6Al-4V ELI Titanium Alloy per ASTM F136 | Polyamide-12 (PA-12) with 316L stainless steel sleeves when used as cutting guides |
| Recommended Temporary Screw Diameter | 1.5mm – 2.1mm | 1.5mm – 2.1mm |
| Recommended Temporary Screw Length | 5mm – 22mm | 5mm – 22mm |
| Recommended Temporary Screw Style | Non-Locking | Drill-Free, Tapping-Free |
| Sterilization | Provided non-sterile and is steam sterilized by the end-user (SAL $10^{-6}$) | Provided non-sterile and is steam sterilized by the end-user (SAL $10^{-6}$) |
| Manufacturing Method | Additive Manufacturing | Additive Manufacturing |
| Patient Contact | Implant – Tissue / Bone; Limited (< 24 hours) | Implant – Tissue / Bone; Limited (< 24 hours) |
| Patient Population | Adults and Pediatrics (12+) | Adults |

## Comparison of Technological Characteristics with the Predicate Device

MedCAD® AccuPlan® Orthopedics System is substantially equivalent to its predicate device (K211614 CenterMed Patient Matched Assisted Surgical Planning (ASP) System).

### Similarities to Predicate

The MedCAD® AccuPlan® Orthopedics 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 including software image transfer, manipulation, and surgical planning. The principles 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 scanner systems (CT)
- System outputs: Additively manufactured physical and/ or digital outputs such as patient-specific anatomical models and surgical guides for use in harvesting bone to support maxillofacial reconstructive surgeries
- Software: Use of commercial off-the-shelf software to support the design phase of the device.
- 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, and guides) for use in maxillofacial 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 only differences between the subject and predicate device relate to the addition of the 12+ pediatric population for the subject device and minor geometrical and material differences. A pediatric risk analysis was performed to support the change in patient population. Performance testing demonstrates that the minor material and geometrical differences do not raise new questions for safety and effectiveness.

## Conclusion

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