March 13, 2025

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

Re: K241811
Trade/Device Name: MedCAD® AccuStride™ 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
Dated: February 7, 2025
Received: February 7, 2025

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241811

Device Name

MedCAD® AccuStride™ System

Indications for Use *(Describe)*

The MedCAD® AccuStride™ System is intended to be used as a surgical instrument to assist in preoperative planning and/or in guiding the marking of bone and/or guide surgical instruments in non-acute, non-joint replacing osteotomies in the foot for adult and pediatric patients 12 years of age and older. The MedCAD® AccuStride™ System surgical guides are intended for single use only. The MedCAD® AccuStride™ System surgical guides should only be used when the anatomic landmarks necessary for pre-operative planning can be clearly identified on the patient's radiographic images (i.e., CT).

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.

K241811
510(k) Summary
MedCAD® AccuStride™ System

March 11, 2025

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

Contacts
Secure BioMed Evaluations
Justin Gracyalny, MSE
7828 Hickory Flat Highway
Suite 120
Woodstock, GA 30188
770-837-2681
Regulatory@SecureBME.com

Name of Device and Classification Name
Device Name: MedCAD® AccuStride™ System
Regulation Name: Orthopaedic Surgical Planning And Instrument Guides
Regulation Number: 888.3030
Product Code: PBF
Classification Panel: Orthopedic

Predicate Device(s)
RedPoint Medical Better Bunion System (K220717)

Reference Device(s)
MedCAD® AccuPlan® Orthopedics System (K223421)
MedCAD® AccuPlan® System (K223024)

Indications for Use:
The MedCAD® AccuStride™ System is intended to be used as a surgical instrument to assist in preoperative planning and/or in guiding the marking of bone and/or guide surgical instruments in non-acute, non-joint replacing osteotomies in the foot for adult and pediatric patients 12 years of age and older. The MedCAD® AccuStride™ System surgical guides are intended for single use only. The MedCAD® AccuStride™ System surgical guides should only be used when the anatomic landmarks necessary for pre-operative planning can be clearly identified on the patient's radiographic images (i.e., CT).

Device Description

The MedCAD® AccuStride™ System is a collection of two individual pieces of software and associated additive manufacturing equipment intended to provide a variety of outputs to support non-acute, non-joint replacing osteotomies in the foot. The system uses electronic medical images of the patient's anatomy or 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, 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. 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.

Sterilization Validation

Sterilization validation information was leveraged from the reference device (K223421). No new testing was required for the subject device.

Biocompatibility Validation

Biocompatibility information was leveraged from the reference device (K223421). No new testing was required for the subject device.

Performance Testing

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

Test	Test Method Summary	Results
Wear Debris Testing (leveraged from K223421)	Cutting / drilling instruments were used on a worst-case titanium surgical guide. The quantity and morphology of wear debris was characterized per ASTM F1877.	**PASS** The wear debris generated by the subject device is less than that reported in the literature to be safe.
Simulated Use Cadaver Validation Testing	Subject devices were manufactured to support simulated surgeries in cadavers. Guides were created to support bunion and metadductus, metatarsal 2+3, akin, and calcaneal osteotomies. Usability and fit was evaluated for all cases. Post-op angle and position data was also collected and compared to pre-surgical plans (bunion and metadductus only).	**PASS** All samples met the predetermined acceptance criteria.

Substantial Equivalence

The MedCAD® AccuStride™ 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. Physical outputs include surgical guides and anatomical models. Biocompatible materials are used in the creation of the subject devices.

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

Property	**MedCAD® AccuPlan® AccuStride™ System**	**RedPoint Medical Better Bunion System K220717**
Indications for Use	The MedCAD® AccuStride™ System is intended to be used as a surgical instrument to assist in preoperative planning and/or in guiding the marking of bone and/or guide surgical instruments in non-acute, non-joint replacing osteotomies in the foot for adult and pediatric patients 12 years of age and older. The MedCAD® AccuStride™ System surgical guides are intended for single use only. The MedCAD® AccuStride™ System surgical guides should only be used when the anatomic landmarks necessary for pre-operative planning can be clearly identified on the patient's radiographic images (i.e., CT).	The Better Bunion System is intended to be used as a surgical instrument to assist in preoperative planning and/or in guiding the marking of bone and/or guide surgical instruments in non-acute, non-joint replacing osteotomies in the foot and ankle for adult and pediatric patients 12 years of age and older. Better Bunion cutting guides are intended for single use only.
Anatomical Location	Foot	Foot and ankle
Preoperative software	Yes	Yes
Data inputs	Images from medical scanners	Images from medical scanners
System Outputs	Surgical guides, anatomical models, and patient-specific case reports	Surgical guides and patient-specific case reports
Materials	Biocompatible polymers and Ti-6Al-4V ELI Titanium Alloy	Ti-6Al-4V ELI Titanium Alloy
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	Externally Communicating – Tissue / Bone / Dentin; Limited (< 24 hours)	Externally Communicating – Tissue / Bone / Dentin; Limited (< 24 hours)

Comparison of Technological Characteristics with the Predicate Device

MedCAD® AccuStride™ System is substantially equivalent to its predicate device (RedPoint Medical Better Bunion System – K220717).

Similarities to Predicate

The MedCAD® AccuStride™ 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: CT Scan Images
- System outputs: Physical and/ or digital outputs such as patient-specific case reports and surgical guides
- Materials: Ti-6Al-4V ELI Titanium Alloy
- Sterility assurance level of $1x10^{-6}$

Differences to Predicate

The subject device includes minor differences in the indications for use. These differences only serve to add clarification for when the device is appropriate for use and do not represent a change to the intended use.

The subject device is similar to that cleared in K220717 with differences including that the subject device uses different software components and also includes positioning verification guides and anatomical models. The inclusion of these components within the subject device system is similar to those cleared in the reference devices (K223421, K223024). Safety and performance testing demonstrate that the addition of these components does not raise new questions for substantial equivalence.

Conclusion

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