March 27, 2026

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

Re: K252064
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 26, 2026
Received: February 26, 2026

Dear Justin 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252064

Please provide the device trade name(s).

MedCAD® AccuStride™ System

Please provide your Indications for Use below.

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 guiding surgical instruments in non-acute, non-joint replacing osteotomies in the foot, ankle, and lower leg (tibia / fibula) 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).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary
MedCAD® AccuStride™ System

February 25, 2026

Sponsor
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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)
MedCAD® AccuStride™ System (K241811)

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 guiding surgical instruments in non-acute, non-joint replacing osteotomies in the foot, ankle, and lower leg (tibia / fibula) 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, ankle, and lower leg (tibia / fibula). 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. 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.

Substantial Equivalence

The MedCAD® AccuStride™ System is identical to the predicate based in terms of indications for use, principles of operation, inputs, and outputs. The only difference is the subject device indications for use includes additional anatomical locations in the ankle and lower leg (tibia / fibula).

Device	**MedCAD® AccuPlan® AccuStride™ System**	**MedCAD® AccuPlan® AccuStride™ System K241811**
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 guiding surgical instruments in non-acute, non-joint replacing osteotomies in the foot, ankle, and lower leg (tibia / fibula) 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 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).
Anatomical Location	Foot, ankle, and lower leg (tibia/ fibula)	Foot
Preoperative software	Yes	Yes
Data inputs	Images from medical scanners (i.e., CT)	Images from medical scanners (i.e., CT)
System Outputs	Surgical guides, anatomical models, and patient-specific case reports	Surgical guides, anatomical models, and patient-specific case reports
Materials	Biocompatible polymers and Ti-6Al-4V ELI Titanium Alloy	Biocompatible polymers and 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, MedCAD® AccuPlan® AccuStride™ System (K241811).

The only difference between the subject and predicate device is the subject device is indicated for use in additional anatomical locations in the ankle and lower leg (tibia / fibula). There are no differences in component design, geometry, materials, sterilization, software, or patient specific design process.

Validation Activities

To address the expansion of indicated osteotomy locations, the following performance testing was conducted.

Test	Test Method Summary	Results
Simulated Use Cadaver Validation	Surgical guides were created to support representative distal, midshaft, and proximal osteotomies in a cadaver model. The final osteotomy positions and wedge angles were measured and compared to the presurgical plan. Guide usability was also evaluated.	**PASS** All samples met the predetermined acceptance criteria.

Conclusion

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