November 4, 2025

MedCAD
℅ Justin Gracyalny
Regulatory Affairs Program Manager
Secure BioMed Evaluations
7828 Hickory Flat Hwy
Suite 120
Woodstock, Georgia 30188

Re: K251709
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, HRS
Dated: October 3, 2025
Received: October 3, 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

# Indications for Use

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| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K251709 |

Please provide the device trade name(s).

MedCAD® AccuStride™ System

Please provide your Indications for Use below.

Surgical Guides and Anatomical Models:
The MedCAD® AccuStride™ System surgical guides and anatomical models are intended to be used as surgical instruments 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 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).

Fixation Plates:
The MedCAD® AccuStride™ System fixation plates are indicated for use in trauma, general surgery, and reconstructive procedures of the foot for adult and pediatric patients 12 years of age and older. The MedCAD® AccuStride™ System fixation plates are intended for single use only. The MedCAD® AccuStride™ System fixation plates 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)

**K251709**
**510(k) Summary**
**MedCAD® AccuStride™ System**

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| **Date Prepared** | October 29, 2025 |
| **Sponsor Contact** | MedCAD<br>501 S 2nd Ave, Suite A-1000<br>Dallas, TX 75226<br>(214) 453-8864 |
| **510(k) Contact(s)** | Secure BioMed Evaluations<br>Justin Gracyalny, MSE<br>7828 Hickory Flat Highway, Suite 120<br>Woodstock, GA 30188<br>770-837-2681<br>Regulatory@SecureBME.com |
| **Trade Name** | MedCAD® AccuStride™ System |
| **Code – Classification** | PBF: Orthopaedic Surgical Planning And Instrument Guides (21 CFR 888.3030)<br>HRS: Plate, fixation, bone (21 CFR 888.3030) |
| **Predicate Devices** | K241811 MedCAD® AccuStride™ System |
| **Additional Predicate** | K131445 OsteoMed ExtremiLOCK Foot Plating System |
| **Reference Devices** | K131670 Zimmer BioMed ALPS Small Bone Locked Plating System<br>K091614 OsteoMed Foot Plating System |
| **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 operations in the foot. The system uses electronic medical images of the patient's anatomy and 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, fixation plates, and patient-specific case reports.<br><br>The MedCAD® AccuStride™ System includes patient specific metal bone plating used in conjunction with commercially available metal bone screws for the fixation to bone in trauma, general surgery, and reconstructive procedures of the foot. The design and dimensions of each plate within the envelope specification is based upon the patient's anatomical data (i.e., CT scan), and the intended anatomy to be fixated as determined from input provided by the surgeon. The subject device is not intended to be bent or modified in surgery. Plates are additively manufactured from Ti-6AL-4V Extra Low Interstitial (ELI) titanium alloy and are provided clean but non-sterile for end-user sterilization. Plates are fastened using commercially available locking and non-locking bone screws with diameters ranging from 2.0mm to 4.0mm and lengths ranging from 10mm to 60mm. Plates have been pre-validated for use with locking and non-locking screws from |

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| | the Osteomed Extremilock Foot Plating System (K131445) and the Osteomed Extremilock Ankle Plating System (K133691). When use of an alternate screw to the pre-validated screw offerings is desired, users must consult the Surgical Technique Guide for information.<br><br>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. |
| **Indications for Use Statement** | Surgical Guides and Anatomical Models:<br>The MedCAD® AccuStride™ System surgical guides and anatomical models are intended to be used as surgical instruments 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 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).<br><br>Fixation Plates:<br>The MedCAD® AccuStride™ System fixation plates are indicated for use in trauma, general surgery, and reconstructive procedures of the foot for adult and pediatric patients 12 years of age and older. The MedCAD® AccuStride™ System fixation plates are intended for single use only. The MedCAD® AccuStride™ System fixation plates 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). |
| **Comparison of Technological Characteristics with the Predicate Device** | The MedCAD® AccuStride™ System is substantially equivalent to its predicate devices (K241811 MedCAD® AccuStride™ System and K131445 OsteoMed ExtremiLOCK Foot Plating System).<br><br>Surgical Guides and Models: The MedCAD® AccuStride™ System surgical guides and anatomical models are identical to those cleared in K241811. There are no differences in these components.<br><br>Fixation Plates: The purpose of this submission was to add fixation plates as a system output, which was not included in the predicate device |

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| | (K241811). K131445 was included as an additional predicate to support the addition of these components.<br>• Similarities: The subject device fixation plates have the same intended use and similar technological characteristics as the identified predicate device (K131445). The devices share the same intended use, principle of operation, and many other similar fundamental technological characteristics such as: material, plate geometry, number of screw holes, compatible screw diameter, and compatible screw length.<br>• Differences: The subject device fixation plates include 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 plates include minor differences in component size, manufacturing technology, and the inclusion of a patient specific design process. These differences are addressed via inclusion of the identified reference devices and supporting non-clinical performance testing. In conclusion, these differences were shown to not raise new questions for substantial equivalence. |
| **Performance Testing** | The MedCAD® AccuStride™ System surgical guides and anatomical models are identical to those cleared in K241811. No new testing was required to support these components.<br><br>The following testing was performed to support the addition of the MedCAD® AccuStride™ System fixation plates or leveraged from previous submissions:<br>• Biocompatibility Testing per ISO 10993-1<br>• Sterilization Validation per ISO 17665-1<br>• Simulated Use Cadaver Validation Testing<br>• Static and Dynamic Bending per ASTM F382<br>• Axial Screw Pushout<br><br>The results of these studies show the MedCAD® AccuStride™ System is substantially equivalent to the predicate devices. |
| **Conclusion** | The MedCAD® AccuStride™ System is substantially equivalent to its predicate device. |