



September 29, 2025

Disior Ltd
% Kelsey Gibson
Regulatory Affairs Specialist
Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, CO 80134

Re: K250023

Trade/Device Name: Smart PCFD
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: August 29, 2025
Received: August 29, 2025

Dear Kelsey Gibson:

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,



Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging Devices and
Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K250023

Device Name

SMART PCFD

Indications for Use (Describe)

SMART PCFD software includes AI-powered algorithms and is intended to be used to support orthopedic healthcare professionals in the diagnosis and surgical planning of Progressive Collapsing Foot Deformity (PCFD) in a hospital or clinic environment. The medical image modality intended to be used in the software is weight-bearing CT (WBCT).

SMART PCFD software provides for the user:

- Visualization report of the three-dimensional (3D) mathematical models and measurements of the anatomical structures of foot and ankle and three-dimensional models of orthopedic fixation devices,
- Measurement templates containing radiographic measures of foot and ankle, and
- Surgical planning application for visualization of foot and ankle anatomical three-dimensional structures, radiographic measures, and surgical instrument parameters supporting the following common flatfoot procedures: Medial Displacement Calcaneal Osteotomy (MDCO), Lateral Column Lengthening (LCL), and Cotton Osteotomy (CO).

The visualization report containing the measurements is intended to be used to support orthopedic healthcare professionals in the diagnosis of PCFD. The surgical planning application contains the visualizations of the three-dimensional structural models, orthopedic fixation device models and surgical instrument parameters combined with the measurements is intended to be used to support orthopedic healthcare professionals in surgical planning of PCFD.

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.

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510(K) SUMMARY

510(k) Number: K250023

Manufacturer: Disior Ltd
HTC Helsinki, Building Pinta, Tammasaarenkatu 3
Helsinki Uusimaa, FL, 00180, Finland

Contact: Markuu Laitinen
Director of Enabling Technology
Phone: +358 405 430 673
Email: mlaitinen@paragon28.com

Prepared By: Kelsey R. Gibson
Regulatory Affairs Specialist II

Paragon 28, Inc.
14445 Grasslands Dr.,
Englewood, CO, 80134
Phone: 720-994-5458

Date Prepared: September 26, 2025

Device TradeName: SMART PCFD

Device Class and Common Name: Class II, Automated Radiological Image Processing Software

Classification: 21 CFR 892.2050: Medical image management and processing system

Product Codes: QIH

Indications for Use: SMART PCFD software includes AI-powered algorithms and is intended to be used to support orthopedic healthcare professionals in the diagnosis and surgical planning of Progressive Collapsing Foot Deformity (PCFD) in a hospital or clinic environment. The medical image modality intended to be used in the software is weight-bearing CT (WBCT).

SMART PCFD software provides for the user:

- Visualization report of the three-dimensional (3D) mathematical models and measurements of the anatomical structures of foot and ankle and three-dimensional models of orthopedic fixation devices,
- Measurement templates containing radiographic measures of foot and ankle, and

- Surgical planning application for visualization of foot and ankle anatomical three-dimensional structures, radiographic measures, and surgical instrument parameters supporting the following common flatfoot procedures: Medial Displacement Calcaneal Osteotomy (MDCO), Lateral Column Lengthening (LCL), and Cotton Osteotomy (CO).

The visualization report containing the measurements is intended to be used to support orthopedic healthcare professionals in the diagnosis of PCFD. The surgical planning application contains the visualizations of the three-dimensional structural models, orthopedic fixation device models and surgical instrument parameters combined with the measurements is intended to be used to support orthopedic healthcare professionals in surgical planning of PCFD.

**Device
Description:**

The SMART PCFD software is intended to be used in reviewing and digitally processing computed tomography images for the purposes of interpretation by a specialized medical practitioner. The device segments the medical images and creates a 3D model of the bones of the foot and ankle. Measurements, including anatomical axes, are provided to the user and the device allows for presurgical planning.

The device includes the same machine learning derived outputs as the primary predicate SMART Bun-Yo-Matic CT (K240642) device and no new validations were conducted.

Details on the previously performed validation are summarized below. The testing for 82 CT image series presented 100% correctly identified bones of foot and ankle. The existence of metal was identified correctly for 98.8% of the images (specificity 98%, sensitivity 100%).

Study Subjects

The AI algorithm for bone identification was developed using 145 CT image studies and metal identification was developed using 130 CT image studies. Testing was carried out using 82 CT image studies. Out of 357 CT image studies, 340 were from individual patients with few studies from same patient with different foot alignments. The CT image series' were collected from various sites across USA and Europe with a minimum of 50% of the images originating from the USA. The CT image studies were from patients with different ages and racial groups, with minimum of 35% male/female within each dataset, with mean age approximately 47 years (SD 15 years), and representatives from White, (Non-)Hispanic, African American, and Native racial groups. Each dataset was balanced in terms of subjects with different foot alignment, demographics, imaging devices and with subjects from clinical subgroups ranging from control/normal feet (44% with test data) to pre-/post-operative clinical conditions such as Hallux Valgus, Progressive Collapsing Foot Deformity, fractures, or with metal implants (40% of the test data).

Imaging Systems

The 357 image studies were collected using CT imaging system made by five (5) manufacturers (7 different models in total). From the test data of 82 images, 61% of the images were acquired using Curvebeam PedCAT, 11% with Planmed Verify, and 26% with Carestream OnSight 3D Extremity. In addition, system test data contains images acquired with Toshiba Somatom. Typical imaging protocol is disclosed within the IFU, however, the test data contains wider range of parameters for generalization (tube

voltages between 90-120 kV, tube currents 5-8 mA, and slice thickness/pixel spacing 0.37-1.5mm).

Ground Truth

The ground truths for bone and metal identification were independently established by three (3) U.S. Orthopedic surgeons with a 3rd party software. Each clinicians reviewed each of the DICOM series through axial/sagittal/coronal views and/or 3D reconstruction and marked on a spreadsheet the presence of a bone and metal in the image series. Based on the majority vote of three, two same responses were required to establish a ground truth on each of the DICOM series.

Training, Tuning, and Validation Data Independence

The SMART PCFD software machine learning algorithm training and tuning data used during the algorithm development, as well as test data used in the standalone software performance assessment study, were all independent data sets. Each CT image study was allowed to be allocated to only data set.

Predicate: SMART Bun-Yo-Matic CT (K240642)

Substantial Equivalence: The Indications for Use of the subject device and the predicate device are similar. Differences do not constitute a different intended use because both devices are intended to provide 3D models, measurements, and presurgical planning generated from CT input to orthopaedic healthcare professionals.

The subject and predicate devices have similar technological characteristics. The main differences being in the surgical planning case report output for the device since the subject device is for Progressive Collapsing Foot Deformity (PCFD) while the predicate device is for Lapidus Arthrodesis. In support of the claim of substantial equivalence the comparison between the subject and predicate systems demonstrates a shared input, image processing, measuring and planning capabilities, and user interface.

	Subject Device	Primary Predicate Device	Additional Predicate Device
Manufacturer	Disior Ltd	Disior Ltd	Disior Ltd
Trade Name	SMART PCFD	SMART Bun-Yo-Matic CT	Bonelogic
510(k)	Subject Device	K240642	K223757
Indications for Use	SMART PCFD software includes AI-powered algorithms and is intended to be used to support orthopedic healthcare professionals in the diagnosis and surgical planning of Progressive Collapsing Foot Deformity (PCFD) in a hospital or clinic environment. The medical image modality intended to be used in the software is weight-bearing CT (WBCT).	SMART Bun-Yo-Matic CT software is to be used by orthopaedic healthcare professionals for diagnosis and surgical planning in a hospital or clinic environment. The medical imaging type intended to be used as the input of the software is Computed Tomography (CT). SMART Bun-Yo-Matic CT software provides: <ul style="list-style-type: none"> • Visualization report of the three-dimensional 	Bonelogic software is to be used by orthopaedic healthcare professionals for diagnosis and surgical planning in a hospital or clinic environment. Bonelogic software provides: <ul style="list-style-type: none"> • Semi-automatic segmentation with manual or assisted input of bony structure identification from CT imaging input,

	<p>SMART PCFD software provides for the user:</p> <ul style="list-style-type: none"> • Visualization report of the three-dimensional (3D) mathematical models and measurements of the anatomical structures of foot and ankle and three-dimensional models of orthopedic fixation devices, • Measurement templates containing radiographic measures of foot and ankle, and • Surgical planning application for visualization of foot and ankle anatomical three-dimensional structures, radiographic measures, and surgical instrument parameters supporting the following common flatfoot procedures: Medial Displacement Calcaneal Osteotomy (MDCO), Lateral Column Lengthening (LCL), and Cotton Osteotomy (CO). <p>The visualization report containing the measurements is intended to be used to support orthopedic healthcare professionals in the diagnosis of PCFD. The surgical planning application contains the visualizations of the three-dimensional structural models, orthopedic fixation device models and</p>	<p>mathematical models of the anatomical structures of foot and ankle and three-dimensional models of orthopaedic fixation devices,</p> <ul style="list-style-type: none"> • Measurement templates containing radiographic measures of foot and ankle, • Surgical planning application for visualization of foot and ankle anatomical three-dimensional structures, radiographic measures, and surgical instrument parameters. <p>The visualization report containing the measurements can be used for the diagnosis of orthopaedic healthcare conditions. The surgical planning application containing the visualizations of the three-dimensional structural models, orthopaedic fixation device models and surgical instrument parameters combined with the measurements can be used for the planning of treatments and operations to correct orthopaedic healthcare conditions of foot and ankle.</p>	<ul style="list-style-type: none"> • Three-dimensional mathematical models of the anatomical structures of foot and ankle, • Measurement templates containing radiographic measures of foot and ankle, and tools for manually obtaining lines and angular measurements, • Surgical planning application for foot and ankle using three-dimensional models of the anatomical structures and radiographic measures. <p>The three-dimensional models of the anatomical structures combined with the measurements can be used for the diagnosis of orthopaedic healthcare conditions. The surgical planning application containing the three-dimensional structural models combined with the measurements can be used for the planning of treatments and operations to correct orthopaedic healthcare conditions of foot and ankle.</p>
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	surgical instrument parameters combined with the measurements is intended to be used to support orthopedic healthcare professionals in surgical planning of PCFD.		
Input	Weight Bearing CT DICOM Computed tomography	Computed tomography DICOM Computed tomography	Computed tomography DICOM Computed tomography
Image Processing	Segmentation of bone structures	Segmentation of bone structures	Segmentation of bone structures
Output	Automated case report of the 3D model of patient anatomy, surgical instrument parameters, and visualization of implant	Automated case report of the 3D model of patient anatomy, surgical instrument parameters, and visualization of implant	3D model of patient anatomy and case report of the 3D model patient anatomy
Measuring and Planning	Perform measurements for presurgical planning	Perform measurements for presurgical planning	Perform measurements for presurgical planning
User Interface	Graphical user interface (GUI) to a web application used with a standard web browser.	Graphical user interface (GUI) to a web application used with a standard web browser.	Graphical user interface (GUI) built on the Unity development engine.

Performance Testing:

Differences do not introduce new questions of safety and effectiveness.

All necessary testing has been performed on the SMART PCFD device to assure substantial equivalence to its predicate and demonstrate the subject device performs as intended.

Software Verification and Validation

Software verification and validation were carried out based on the “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”, at the unit, integration, and system levels to determine substantial equivalence to the predicate device.

Non-Clinical Bench Testing

Performance testing was conducted to evaluate the Surgical Planning Component of the device. The Surgical Planning Component was tested with multiple images and appropriate outputs for the subject device were evaluated by qualified truthers. Results showed the subject device performed as intended. Surgery planning executes mathematical operations for estimated correction ± 1 degree for angular measurements and ± 1.0 mm for distance measurements.

Conclusions:

Clinical data are not needed to support the safety and effectiveness of the subject device. The SMART PCFD device subject to this submission possesses the same intended use and has similar technological characteristics as the predicate device. All performance testing conducted for the SMART PCFD device met the predetermined acceptance criteria or were otherwise considered acceptable. As such, the SMART PCFD device is substantially equivalent to the predicate device for the intended use.