



Disior Ltd
% Haylie Fast
Manager of Regulatory Affairs
Paragon 28, Inc.
14445 Grasslands Dr.
Englewood, Colorado 80134

June 20, 2024

Re: K240642
Trade/Device Name: SMART Bun-Yo-Matic CT
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: March 6, 2024
Received: May 22, 2024

Dear Haylie Fast:

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.

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
Assistant Director

Imaging Software Team

DHT8B: Division of Radiologic 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)

K240642

Device Name

SMART Bun-Yo-Matic CT

Indications for Use (Describe)

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:

- Visualization report of the three-dimensional mathematical models of the anatomical structures of foot and ankle and three-dimensional models of orthopaedic fixation devices,
- 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.

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.

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: K240642

Manufacturer: Disior Ltd
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Phone: 720-994-5489

Date Prepared: May 21, 2024

Device Trade Name: SMART Bun-Yo-Matic CT

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 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:

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- 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.

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.

**Device
Description:**

The SMART Bun-Yo-Matic CT device is an automatic software tool that segments foot and ankle bones from computed tomography (CT) images and provides a case report showing images of a 3D model of the segmented structures with pre-operative and post-correction measurements. The correction is for hallux valgus through a Lapidus Arthrodesis procedure. The case report also provides parameters of an orthopedic surgical instrument and an example of an implant construct for the procedure.

The device includes machine learning derived outputs. Details on the 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 Bun-Yo-Matic CT 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: Bonelogic (K223757)

**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 are in the output and user interface. In support of the claim of substantial equivalence the comparison between the subject and predicate systems demonstrates a shared input, image processing, and measuring and planning capabilities.

	Subject Device	Primary Predicate Device
Manufacturer	Disior Ltd	Disior Ltd
Trade Name	SMART Bun-Yo-Matic CT	Bonellogic
510(k)	Subject Device	K223757
Input	Computed tomography DICOM Computed tomography	Computed tomography DICOM Computed tomography
Image Processing	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	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
User Interface	Graphical user interface (GUI) to a web application used with a standard web browser.	Graphical user interface (GUI) that is standalone application based.

Differences do not introduce new questions of safety and effectiveness.

Performance Testing:

All necessary testing has been performed on the SMART Bun-Yo-Matic CT 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. For image analytics, the predicate device meets the subject device’s established acceptance criteria of 95% model conformance within 1.0mm distance to reference model and 2.0 degrees standard deviation for angular measurements. Surgery planning executes mathematical operations for estimated correction ± 1 degree for angular measurements and ± 1.0 mm for distance measurements.

Non-Clinical Bench Testing

Performance testing was conducted to evaluate the AI/ML Component, the Segmentation Component, and the Surgical Planning Component of the device. Each 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.

Clinical data are not needed to support the safety and effectiveness of the subject device.

Conclusions: The SMART Bun-Yo-Matic CT 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 Bun-Yo-Matic CT device met the predetermined acceptance criteria or were otherwise considered acceptable. As such, the SMART Bun-Yo-Matic CT device is substantially equivalent to the predicate device for the intended use.