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

July 2, 2024

Re: K240736
Trade/Device Name: SMART Bun-Yo-Matic X-Ray
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH
Dated: March 18, 2024
Received: June 3, 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, PhD
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

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)*

K240736

Device Name

SMART Bun-Yo-Matic X-Ray

Indications for Use *(Describe)*

SMART Bun-Yo-Matic X-Ray 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 X-ray.

The SMART Bun-Yo-Matic X-Ray software provides:

• Visualization report of the three-dimensional mathematical models of the anatomical structures of the 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 measurements in the context of three-dimensional structural models, orthopaedic fixation device models and surgical instrument parameters 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.

510(K) SUMMARY

510(k) Number: K240736

Manufacturer: Disior Ltd
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Helsinki Uusimaa, FL, 00180, Finland

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Prepared By: Haylie Fast
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14445 Grasslands Dr.,
Englewood, CO, 80112
Phone: 720-994-5489

Date Prepared: March 31, 2024

Device Trade Name: SMART Bun-Yo-Matic X-RAY

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 X-Ray 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 X-ray.

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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 measurements in the context of three-dimensional structural models, orthopaedic fixation device models and surgical instrument

parameters 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 X-Ray device is a software tool that takes x-rays of the foot and produces 3D axes on contextual bone models to help a user plan for hallux valgus correction. The final output of the device is a case report that provides images of the patient's axes, as well as measurements prior to correction and following a surgical correction selected by the user.

The device uses machine learning derived outputs. Details on the validation are summarized below. The testing of the algorithm included 97 images that were a combination of plain-film native x-ray images and Cone Beam Computed Tomography (CBCT) Digitally Reconstructed Radiographs (DRR) from CT images series.

Study Subjects

The AI algorithm for bone identification was developed using 1,5776 x-ray and CBCT DRR and metal identification was developed using 15 x-ray and CBCT DRR. Testing was carried out using 97 x-ray and DRR. Out of 97 image studies, 42 were from individual patients with some studies from same patient with different foot alignment or laterality. The x-ray and CBCT DRR were collected from various sites across USA, Germany, UK, Finland, and Korea. The x-ray and CBCT DRR were collected from patients with different ages and racial groups, with minimum of 5% male/female within each dataset, with mean age approximately 35 years, and representatives from White (Non-)Hispanic, Hispanic, and Native American 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 to pre-/post-operative clinical conditions such as Hallux Valgus, and undefined indications.

Imaging Systems

The 97-image x-ray and DRR test set was collected from five (5) different systems from five (5) different manufacturers. This set of five (5) imaging systems contained three (3) x-ray and two CBCT DRR machines. From the total test data 31% of the images were collected from a Siemens – Aristos and Ysio X-Pree X-ray system, 13% were collected from an iRAy Gamma X-ray system 1% were collected from a Swissray Medical AG ddR Element System X-ray system, 53% were collected from a Carestream OnSight 3D Extremity Scanner CBCT DRR, and 2% were collected from a CurveBeam PedCAT CBCT DRR.

Ground Truth

The ground truth for the testing data was established by 2 (2) clinicians with over five (5) years of experience practicing medicine. Each clinician was given the same image data to review

dorsoplantar and lateral x-ray images. Each clinician then marks on a spreadsheet the presence of the bone in the image.

Training, Tuning, and Validation Data Independence
The SMART Bun-Yo-Matic X-ray 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 x-ray or CBCT DRR 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. Both devices are intended to take medical imaging as an input and provide measurements from 3D structures to assist in surgical planning. The predicate device does this through the 3D model, and the subject device shows axes of patient anatomy in the context of a generic bone model through a series of images.

The subject and predicate devices have similar technological characteristics. The primary differences are the images needed as the input, the output of the software, the user interface and the items provided in the presurgical planning capabilities. In support of the claim of substantial equivalence the comparison between the subject and predicate systems, performance testing has been done to demonstrate that the differences do not introduce new questions of safety and effectiveness.

	Subject Device	**Primary Predicate Device**
Manufacturer	**Disior Ltd**	**Disior Ltd**
Trade Name	**SMART Bun-Yo-Matic X-Ray**	**Bonelogic**
510(k)	Subject Device	K223757
Input	Weight-bearing plain film X-Rays from sagittal and transverse views	Computed tomography DICOM Computed tomography
Output	Automated case report of the 3D axes of patient anatomy, surgical instrument parameters, and visualization of implant	3D model of patient anatomy, automated case report
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.

Performance Testing: All necessary testing has been performed on the SMART Bun-Yo-Matic X-ray 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 subject device meets the predicates 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.

Performance Testing
Performance testing was conducted. Testing included the following:

- AI/ML Testing.
- Comparison of the 2D-3D construction to manual measurements as well as ground truth.
- Comparison of the clinical acceptability of axes placement.
- Comparison of the planned surgical correction to the actual surgical correction.

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 X-Ray device subject to this submission possesses similar intended use and has similar technological characteristics as the predicate device, where the differences are shown through performance testing to not raise questions of safety and effectiveness. All performance testing conducted for the SMART Bun-Yo-Matic X-Ray device met the predetermined acceptance criteria or were otherwise considered acceptable. As such, the SMART Bun-Yo-Matic X-Ray device is substantially equivalent to the predicate device for the intended use.