Disior Ltd
% Alex Cadotte
Associate Director, Software and Digital Health Regulatory Affairs
Mcra, LLC
1050 K St NW Suite 1000
Washington, DC 20001

December 8, 2023

Re: K223757
Trade/Device Name: Bonelogic
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: QIH
Dated: November 7, 2023
Received: November 13, 2023

Dear Alex Cadotte:

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
Iamging Sofware 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223757

Device Name
Bonelogic 2.2

Indications for Use *(Describe)*
Bonelogic software is to be used by orthopaedic healthcare professionals for diagnosis and surgical planning in a hospital or clinic environment.
Bonelogic software provides:
• Semi-automatic segmentation with manual or assisted input of bony structure identification from CT imaging input,
• 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 linear and angular measurements,
• Surgical planning application for foot and ankle using three-dimensional models of the anatomical structures and radiographic measures.
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.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Device Trade Name: Bonelogic 2.2

Manufacturer: Disior Ltd
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Date Prepared: December 7, 2023

Classifications: 21 CFR 892.2050 Medical image management and processing system.

Class: II

Product Code: QIH

Primary Predicate: K203290

Indications For Use:
Bonelogic software is to be used by orthopaedic healthcare professionals for diagnosis and surgical planning in a hospital or clinic environment.
Bonelogic software provides:

- Semi-automatic segmentation with manual or assisted input of bony structure identification from CT imaging input,
- 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 linear and angular measurements,
- Surgical planning application for foot and ankle using three-dimensional models of the anatomical structures and radiographic measures.

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.

Device Description:
The Bonelogic is a software tool that segments bone anatomy using dedicated semi-automatic tools and fully automatic algorithms. More specifically, Bonelogic is intended to segment foot and ankle bones from computed tomography (CT) images. The segmented structures may then be used to create 3D models of their respective bones and replicate the anatomy of a patient. The semi-automatic tools of the software require a healthcare professional to mark the different bones in an initial 3D rendered model prior to when the segmentation process is initialized. This method is called the semi-automatic workflow with manual input. The software also comprises an optional semiautomatic workflow with assisted input that replaces the required user input with an estimate based on a locked artificial neural network (ANN) model. The fully automatic algorithm processes the final result in the same way based on input generated by the semi-automatic workflow with user input and with ANN model. The user still needs to mark the laterality and as a new step acknowledge the bones discovered by the ANN model.

Predicate Device:
Disior submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, K223757 is substantially equivalent in indications, design principles, and performance to the following subject device:

Substantial Equivalence:

Information	Predicate Device K203290 (Bonelogic)	Subject Device K223757 (Bonelogic 2.2)	Comparison
Classification Name	Medical image management and processing system	Medical image management and processing system	Identical
Service Type	Software	Software	Identical
Classification	21 CFR 892.2050	21 CFR 892.2050	Identical
Class	II	II	Identical
Product Code	LLZ	QIH	Identical
Indications for Use	Bonelogic software is intended to be used by specialized medical practitioners to assist in the characterization of human anatomy with 3D visualization and specific measurements. The medical image modalities intended to be used in the software are computed tomography (CT) images, cone beam computed tomography (CBCT) images and weight-bearing cone beam CT (WBCT) images. The intended patient population is adults over 16 years of age. Bonelogic software contains the measurement template	Bonelogic software is to be used by orthopaedic healthcare professionals for diagnosis and surgical planning in a hospital or clinic environment. Bonelogic software provides: Semi-automatic segmentation with manual or assisted input of bony structure identification from CT imaging input, 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	Removal of wrist and hand related functionality and addition of an optional semiautomatic segmentation workflow with assisted bone identification process in the subject device

Information	Predicate Device K203290 (Bonelogic)	Subject Device K223757 (Bonelogic 2.2)	Comparison
	with a set of distance and angular measures. The measurements can be used for diagnostic purposes. The three-dimensional (3D) models are displayed and can be manipulated in the software. Together, the information from the measurements and the 3D visualization can be used for treatment planning in the field of orthopedics (foot and ankle, and hand and wrist). The 3D models can be outputted from the software for traditional or additive manufacturing. The physical models generated based on the 3D digital models are not intended for diagnostic use.	obtaining linear and angular measurements, Surgical planning application for foot and ankle using three-dimensional models of the anatomical structures and radiographic measures. 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.	
Input	Computed tomography DICOM images	Computed tomography DICOM Computed tomography	Identical
Image processing	Segmentation of bone structures	Segmentation of bone structures	Identical
Output	3D model of patient anatomy	3D model of patient anatomy	Identical
Measuring and planning	Perform measurements for presurgical planning	Perform measurements for presurgical planning	Identical
Bone identification	Manual process	Manual and an optional semiautomatic workflow with assisted input process performed by artificial neural network	Optional semiautomatic bone identification process in subject device

Performance Testing Summary:

- **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. 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.
- **Bench testing** – Software verification and validation for Bonelogic software demonstrated its substantial equivalence to the predicate device. An additional clinical data based software performance assessment study was carried out to validate the standalone performance of AI algorithms from a clinical perspective. 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 Bonelogic 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.

Conclusion:
The subject device and the predicate devices have the same intended use and have similar technological characteristics. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. Bonelogic 2.2 is as safe, as effective, and performs as well as, or better, than the predicate devices.