Disior Oy (Ltd.)
℅ Markku Laitinen
COO
Lapinlahdenkatu 16
Helsinki, 00180
FINLAND

February 5, 2021

Re: K203290
Trade/Device Name: Bonelogic
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 6, 2020
Received: November 9, 2020

Dear Markku Laitinen:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K203290

Device Name
Bonelogic

Indications for Use *(Describe)*
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 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.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

Disior Oy
Maria 01, Building 2
Lapinlahdenkatu 16
00180 Helsinki Finland
www.disior.com

# 510(k) Summary

510 (k) number: K203290

Dated: January 12th, 2021

The following section is included as required by the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92.

| | |
|---|---|
| Company Name: | Disior Oy |
| Establishment Registration Number: | N/A |
| Street Address: | Lapinlahdenkatu 16 |
| City: | Helsinki |
| Postal Code: | 00180 |
| Country: | FINLAND |
| Phone Number: | +358 405430673 |
| Principal Contact Person: | Markku Laitinen |
| Contact email: | markku@disior.com |

## Submission information

| | |
|---|---|
| Trade Name: | Bonelogic |
| Common Name: | Image Processing System |
| Classification Product Name: | System, Image processing, Radiological |
| Classification Product Code: | LLZ (892.2050) |

## Predicate device

The primary predicate device to which substantial equivalence is claimed:

| | |
|---|---|
| 510(K) No. | K183105 |
| Clearance Date: | March 27, 2019 |
| Device Name: | Mimics Medical |
| Manufacturer: | Materialise N.V. |
| Classification Product Name: | System, Image processing, Radiological |
| Classification Product Code: | LLZ (892.2050) |

Disior Oy
Maria 01, Building 2
Lapinlahdenkatu 16
00180 Helsinki Finland
www.disior.com

## Description and functioning of the device

Bonelogic product is a software tool to be used by specialized medical practitioners. The software tool is aimed to help the user in the characterization of human anatomy, and identifying possible trauma or deformities, the diagnose and the treatment planning should always be based on the professional skills of the specialist doctor. 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. Bonelogic software has got a modular architecture. The software includes following functionality:

- Importing medical images in DICOM format
- Viewing of DICOM data
- Selecting a region of interest using generic segmentation tools
- Segmenting specific anatomy using dedicated semi-automatic tools or fully automatic algorithms
- Verifying and editing a region of interest
- Calculating a digital 3D model and editing the model
- Measuring on 3D models
- Exporting images, measurements, and 3D models to third-party packages
- Planning treatments on the 3D models
- Interfacing with packages for Finite Element Analysis

## Intended 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.

## Indications for use

Bonelogic software contains the measurement template 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.

Disior Oy
Maria 01, Building 2
Lapinlahdenkatu 16
00180 Helsinki Finland
www.disior.com

## Comparison of Technological Characteristics with the Predicate Device

The subject device Bonelogic employs similar fundamental technologies as the predicate device.

Technological similarities include:

- Device functionality:
  - Image segmentation: The subject and predicate device share the same image segmentation functionalities.
  - Processing to output file: The subject and predicate device both generate an output file.
  - Measuring and planning: The subject and predicate device both have functionalities to perform measurements and pre-surgical planning.

The following technological differences exist between the subject device and the predicate device:

- Imaging information:
  - Whereas the predicate device is more generally intended to import imaging information of a medical scanner, allowing both DICOM compatible images and standard imaging formats (such as RAW, TIFF, BMP and JPEG), the subject device is intended to import only DICOM compliant types.
- Device functionalities:
  - Whereas the predicate device is creating Python scripts to automate workflows, the subject device is not supporting Python scripts.
- Device design:
  - The design of the predicate device is organized in a toolbox fashion with manual steps in tissue segmentation and manual measurement tools, whereas the interface of the subject device specifically guides the user through a few predefined steps for obtaining a 3D output file and defined measurements.

Disior Oy
Maria 01, Building 2
Lapinlahdenkatu 16
00180 Helsinki Finland
www.disior.com

## Performance data

Software verification and validation were performed, and documentation was provided following the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". This includes:

- Subject device comparison with predicate device by comparing the geometric accuracy of outputted 3D models
- Subject device comparison with predicate device by comparing repeatability of manual measurements and measurements created with subject device on radiographical parameters
- Verification for the subject device against defined requirements via performance testing and clinical validation
- Validation for the subject device against user needs via clinical validation on usability of 3D models in clinical setting

End-user validation, clinical validation, and performance testing were performed.

The geometric accuracy of 3D virtual models created in the subject device Bonelogic software was assessed against similar virtual models created with predicate device. The comparison was made with DICOM images containing foot and ankle anatomy.

The measurement accuracy in the subject device Bonelogic software was assessed by comparing manual measurements of radiographical parameters against same measurements created in subject device. The manual measurements were performed by clinicians. The data set in the study included DICOM images containing hand and wrist anatomy.

The verification and validation of the subject device against defined requirements and against user need, was done via performance testing on measurements repeatability and with clinical validation for the accuracy of the 3D virtual models against original DICOM imaging data.

In conclusion, all performance testing conducted demonstrated device performance and substantial equivalence to the predicate device.

## Summary

A comparison of intended use and technological characteristics combined with performance data demonstrates that Bonelogic software is substantially equivalent to the predicate device Mimics Medical (K183105). Minor differences in intended use and technological characteristics exist, but performance data demonstrates that Bonelogic software is as safe and effective and performs as well as the predicate device.