



3D-Side SA
% Mieke Janssen
Regulatory Affairs Consultant
OrthoGrow NV
Davincilaan 1
Zaventem, Vlaams-Brabant 1930
BELGIUM

Re: K221432

August 3, 2022

Trade/Device Name: Customize
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH,
Dated: July 8, 2022
Received: July 11, 2022

Dear Mieke Janssen:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT 8B: Division of Radiological Imaging
Devices and Electronic Products
OHT 8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K221432

Device Name

Customize

Indications for Use (Describe)

Customize for ankle arthroplasty is intended to be used as a software interface to assist in:

- Visualization, modification, validation of the planning of total ankle arthroplasty
- Communication of treatment options
- Segmentation of CT-scan data
- 3D CAD models generation
- use x-ray scan information to enhance the planning of ankle arthroplasty
- Managing timeline and cases

Customize is not intended to be used for

- Spine surgeries
- Implant and instrument design

Experience in usage and clinical assessment are necessary for a proper use of the software. It is to be used for adult patients only and should not be used for diagnostic purposes.

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 (21CFR807.92)

K221432

SUBMITTER

Company Name: 3D-Side
Establishment registration number: 3013561205
Address: Rue André Dumont 5
1435 Mont-Saint-Guibert, BE
Phone number: +32 (0) 10 81 35 48
Principal contact person: Mieke Janssen
Principal contact e-mail address: mieke@ortho-grow.com
Additional contact person: Laurent Paul
Additional contact e-mail address: lp@3dside.eu
Summary date:

DEVICE

Name & trade name: Customize
Classification name: Automated Radiological Image Processing Software
Classification product code: QIH
Regulation number: 21 CFR 892.2050

PREDICATE AND REFERENCE DEVICES

The predicate device to which substantial equivalence is claimed:

Item	Description
Device Classification Name	Automated Radiological Image Processing Software
510(k) number	K213779
Trade or proprietary or model name	Customize
Original Applicant	3D-Side SA
Regulation Number	21 CFR 892.2050
Decision date	March 16, 2022
Classification product code	QIH
510(k) Review Panel	Radiology

DESCRIPTION AND FUNCTIONING OF THE DEVICE

Customize is intended to be used during the preparation of ankle arthroplasties. It visualizes surgical treatment options that were previously created based on 3D CAD files generated from multi-slice DICOM data from a CT scanner. It consists of a single software user interface where the physician can review the CAD files in 3D, CT and X-Ray images in 2D and modify the position

and orientation of the different 3D objects. Customize includes an implant library with 3D digital representations of various implant models so that the right implant positioning and sizing can be achieved based on the physician's input. After approval by the physician, the treatment plan is saved on the server and can be used as a reference during surgery. It is also possible to export the treatment plan for further processing such as designing and manufacturing of patient specific devices (the design of those later is done using an external software).

Customize is prescription use only.

INTENDED USE

Customize for ankle arthroplasty is intended to be used as a software interface to assist in:

- Visualization, modification, validation of the planning of ankle arthroplasty
- Communication of treatment options
- Segmentation of CT-scan data
- 3D CAD models generation
- Use X-Ray images to enhance the planning of ankle arthroplasty
- Managing timeline and cases

Customize is not intended to be used for

- Spine surgeries
- Implant, instrument or patient-specific devices design

Experience in usage and clinical assessment are necessary for a proper use of the software. It is to be used for adult patients only and should not be used for diagnostic purposes.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Following similarities exist between the subject device Customize and the predicate device (Customize, K213779):

- Intended use/indications for use: both the subject and the predicate device share the same intended use
- Device functionality:
 - o Both devices read and visualize medical images compliant with the DICOM standard, and visualize 3D objects.
 - o Both devices implement artificial intelligence including nonadaptive machine learning, followed by human supervision.
 - o Both devices use 3D rendering to visualize the treatment options, and allow preview of the implant replacement components intraoperatively.

Following technological difference exists between the subject device and the predicate device:

- Next to CT imaging data as input for the generation of 3D CAD models, the subject device also uses information from x-ray images as input for the pre-operative planning.

Since the fundamental technologies are similar, no new or different questions of safety or effectiveness are raised. Both the subject as well as predicate device visualize x-ray images, therefore the use of landmark information to calculate parameters for the preoperative planning does not raise different questions of safety and effectiveness.

SUMMARY OF PERFORMANCE DATA

Non-clinical performance data was included in the 510(k)-submission demonstrating Customize has been validated for its intended use and substantial equivalence to the predicate device.

Software verification and validation were performed, and documentation was included in this submission in accordance with FDA Guidance “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”. This includes verification against defined requirements, and validation against user needs. In addition, performance testing included 1) segmentation validation of the Customize software, 2) Repeatability and Reproducibility (R&R) study on the segmentation of ankle anatomies and 3) accuracy study on 3D model generation for tibia and talus.

For image segmentation, the device includes artificial intelligence including nonadaptive machine learning followed by human supervision by a 3D-Side engineer. The AI-based ankle algorithm is based on a machine that has been trained to identify bones using a dataset of 126 medical images (CT scans) and their corresponding segmentation. A proportion of 30% of the cases are eligible for ankle arthroplasty surgery, 70% are cadaveric cases. No confounder is available in the dataset. The population consists of 32% of women, and 68% of man, with an average age of 62 years old. The machine produces a temporary label to the user which should be seen as an initialization to the segmentation which requires manual editions.

CONCLUSION

The characteristics that determine the functionality and performance of Customize, the subject device, are substantially equivalent to the predicate device cleared under K213779. The non-clinical testing indicates that the subject device is as safe, as effective, and performs as well as the predicate.