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

March 16, 2022

Re: K213779
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: February 17, 2022
Received: February 18, 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
Associate 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213779

Device Name
Customize

Indications for Use *(Describe)*
Customize for shoulder arthroplasty is intended to be used as a software interface to assist in:
- Visualization, modification, validation of the planning of shoulder arthroplasty
- Communication of treatment options
- Segmentation of CT-scan data
- 3D CAD models generation
- 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.

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

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510(K) SUMMARY (21CFR807.92)

SUBMITTER

Company Name:	3D-Side
Establishment registration number:	3013561205
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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: March 14, 2022

DEVICE

Name & trade name:	Customize
Classification name:	Automated Radiological Image Processing Software
Classification product code	QIH

PREDICATE AND REFERENCE DEVICES

The predicate device to which substantial equivalence is claimed:

Trade or proprietary or model name	Preview Shoulder
510(k) number	K210556
Decision date	21 April 2021
Classification product code	QIH
Manufacturer	Genesis Software Innovations

DESCRIPTION AND FUNCTIONING OF THE DEVICE

Customize is intended to be used during the preparation of shoulder 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 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.

Customize is prescription use only.

INTENDED USE

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

- Visualization, modification, validation of the planning of shoulder arthroplasty
- Communication of treatment options
- Segmentation of CT-scan data
- 3D CAD models generation
- Managing timeline and cases

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- Spine surgeries
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Experience in usage and a 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.

TECHNOLOGICAL CHARACTERISTICS

Comparison of technological characteristics with the predicate device (Preview Shoulder, K210556):

- Following similarities exist between the subject device Customize and the predicate device:
  - Intended use/indications for use: both the subject and the predicate device share a similar intended use
  - Patient population: both devices are applicable for adult population only
  - Device functionality: both devices enable visualization of medical images (DICOM), include an implant library, and allow implant visualization in both the original scan images as well as the 3D model reconstruction. Both devices utilize image segmentation and allow 3D view manipulation.
- The following technological difference exists between the subject device and the predicate device:
  - The subject device includes a distance map providing an approximate estimate of the distance between two objects. This functionality is absent in the predicate device.

    This difference in technological characteristics does not raise new questions of safety and effectiveness.

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 was performed, and documentation was provided following the "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 study on the segmentation of shoulder anatomies and 3) accuracy study on 3D model generation for humerus and scapula.

SUMMARY

The characteristics that determine the functionality and performance of Customize, the subject device, are substantially equivalent to the predicate device cleared under K210556. The non-clinical testing indicates that the subject device is as safe, as effective, and performs as well as the predicate.