November 29, 2021

3D-Side SA
% Niels Festjens
Regulatory Affairs Consultant
OrthoGrow NV
Davincilaan 1
Zaventem, Vlaams-Brabant 1930
Belgium

Re: K212237
Trade/Device Name: 3D-Cut
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PBF
Dated: August 30, 2021
Received: August 31, 2021

Dear Niels Festjens:

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

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic Devices
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)*
K122237

Device Name
3D-Cut

Indications for Use *(Describe)*
3D-Cut is intended to be used as a surgical instrument to assist in preoperative planning and/or in guiding the marking of bone and/or in guiding surgical instruments in non-acute, non-joint replacing osteotomies, including the resection of bone tumors, for femur, tibia and pelvis including sacrum.

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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K212237

510(K) SUMMARY (21CFR807.92)

SUBMITTER

Company Name:	3D-Side
Establishment registration number:	3013561205
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Additional contact person:	Laurent Paul
Additional contact e-mail address	lp@3dside.eu
Additional contact person:	Niels Festjens
Additional contact e-mail address	niels@ortho-grow.com

Summary date: November 24, 2021

DEVICE

Name & trade name:	3D-Cut
Classification name:	888.3030 - Orthopaedic surgical planning and instrument guides
Classification product code:	PBF

PREDICATE AND REFERENCE DEVICES

The predicate device to which substantial equivalence is claimed:

Trade or proprietary or model name	**VSP® Orthopedics**
510(k) number	K190044
Decision date	August 21, 2019
Classification product code	PBF
Manufacturer	3D Systems, Inc.

Reference device:

Trade or proprietary or model name	**KLS Martin Individual Patient Solutions (IPS) Planning System**
510(k) number	K192979
Decision date	March 11, 2020
Classification product code	PBF
Manufacturer	KLS-Martin L.P.

Trade or proprietary or model name	**FINE Osteotomy Around The Knee**
510(k) number	K193614
Decision date	March 25, 2020
Classification product code	HRS, HWC, PBF
Manufacturer	Bodycad Laboratories, Inc.

DESCRIPTION AND FUNCTIONING OF THE DEVICE

3D-Cut is a patient-matched additively manufactured single use surgical instrument (PSI). Based on a preoperative planning, the instruments are intended to assist physicians in guiding the marking of bone and guiding surgical instruments in bone tumor resection surgery, excluding joint replacement surgeries.

The 3D-Cut instruments are designed starting from patient medical images, computed tomography (CT) and magnetic resonance imaging (MRI) device. The clinician delineates the tumor on the MRI. MRI and the delineated tumor are merged onto the CT which is used to extract the 3D CAD model of the bone. A draft treatment plan is submitted for evaluation to the treating clinician. Upon surgeon's approval, a PSI is designed and again submitted to the clinician. After validation, the PSI is produced using additive manufacturing.

INDICATIONS FOR USE

3D-Cut is intended to be used as a surgical instrument to assist in preoperative planning and/or in guiding the marking of bone and/or in guiding surgical instruments in non-acute, non-joint replacing osteotomies, including the resection of bone tumors, for femur, tibia and pelvis including sacrum.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device 3D-Cut has either identical or substantially equivalent intended use and technological features as the predicate device K190044. Both devices differ in covered anatomical regions and patient population with the subject device covering more anatomical regions and indicated to be used for adults and adolescents. A comparison with the reference devices, risk analysis, and verification and validation testing were used to evaluate the potential impact on substantial equivalence.

SUMMARY OF PERFORMANCE DATA

Several tests have been conducted to demonstrate the output of the manufacturing process conforms to the device specifications. A combination of bench, cadaveric and clinical (OUS published case series) testing was executed to demonstrate the subject device is substantially equivalent to the predicate device and performs in accordance with its intended use.

Testing included biocompatibility testing in accordance with ISO 10993, testing for cleaning, sterility, dimensional stability and packaging, mechanical testing and simulated use testing on cadaveric specimen. In addition, results from clinical investigations using 3D-Cut have been reported.

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".

CONCLUSION

The characteristics that determine the functionality and performance of 3D-Cut, the subject device, are substantially equivalent to the predicate device cleared under K190044. The testing indicates that the subject device is as safe, as effective, and performs as well as the predicate.