



3D Systems, Inc.
% Kim Torluemke
VP Quality & Regulatory, Healthcare
5381 South Alkire Circle
LITTLETON, CO 80127

August 28, 2019

Re: K183489

Trade/Device Name: D2P
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 16, 2019
Received: July 18, 2019

Dear Kim Torluemke:

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 and Part 809); 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

Indications for Use

510(k) Number (if known)
K183489

Device Name
D2P

Indications for Use (Describe)

The D2P software is intended for use as a software interface and image segmentation system for the transfer of DICOM imaging information from a medical scanner to an output file. It is also intended as pre-operative software for surgical planning. For this purpose, the output file may be used to produce a physical replica. The physical replica is intended for adjunctive use along with other diagnostic tools and expert clinical judgement for diagnosis, patient management, and/or treatment selection of cardiovascular, craniofacial, gastrointestinal, genitourinary, neurological, and/or musculoskeletal applications.

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

1. INTRODUCTION

This document contains the 510(k) summary for the D2P software. The content of this summary is based on the requirements of 21 CFR 807.92.

2. SUBMITTER

Name: Simbionix LTD a 3D Systems Company

Address: Beit Golan
Corner of Golan and Hanegev St.
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Phone: +972-3-9114444
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Official Contact: Kim Torluemke
Vice President, Quality and Regulatory, Healthcare

Date Prepared: July 16, 2019

3. DEVICE

Trade Name: D2P

Common Name: Image processing system

Classification Name: System, Image Processing, Radiological

Classification: Class II, 21 CFR 892.2050

Product Code: LLZ

4. PREDICATE DEVICE

The D2P software is claimed to be substantially equivalent to the following legally marketed predicate device:

- D2P, Simbionix LTD a 3D Systems Company (K161841)

Reference device:

- InPrint, Materials N.V. (K173619)

5. DEVICE DESCRIPTION

The D2P software is a stand-alone modular software package that provides advanced visualization of DICOM imaging data. This modular package includes, but is not limited to the following functions:

- DICOM viewer and analysis
- Automated segmentation
- Editing and pre-printing
- Seamless integration with 3D Systems printers
- Seamless integration with 3D Systems software packages
- Seamless integration with Virtual Reality visualization for non-diagnostic use.

6. INDICATIONS FOR USE

The D2P software is intended for use as a software interface and image segmentation system for the transfer of DICOM imaging information from a medical scanner to an output file. It is also intended as pre-operative software for surgical planning. For this purpose, the output file may be used to produce a physical replica. The physical replica is intended for adjunctive use along with other diagnostic tools and expert clinical judgement for diagnosis, patient management, and/or treatment selection of cardiovascular, craniofacial, gastrointestinal, genitourinary, neurological, and/or musculoskeletal applications.

The Indications for Use statement for the D2P software is nearly identical to the predicate device. The primary difference, confirmed through bench testing, includes the ability to utilize the electronic output to print physical anatomic models on qualified 3D Printing technologies and materials for diagnostic use. Both the subject and predicate devices have the same intended use for visualization, analysis and segmentation of medical images and rendering 3D objects.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The D2P software employs the same fundamental technologies as the identified predicate devices, including:

- Viewing of medical imaging data in the axial, coronal and sagittal views
- Ability to process, review and analyze medical imaging data;
- Image transfer and manipulation via software used for the creation of a 3D object;

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

- Incorporation of a deep learning neural network used to create the prediction of the segmentation.
- The ability to remove images from a DICOM dataset.

- The addition of a measurement tool into VR visualization.
- The subject device's intended use explicitly reflects 3D printing of the output file which can be used for diagnostic purposes in cardiovascular, craniofacial, gastrointestinal, genitourinary, neurological, and/or musculoskeletal applications.

8. PERFORMANCE DATA

Non-clinical tests

The D2P application has been validated for its intended use to determine substantial equivalence to the predicate device. A measurement accuracy and calculation 3D study, usability study, and decimation study were performed and confirmed to be within specification. Validation of printing of physical replicas was performed and demonstrated that anatomic models for cardiovascular, craniofacial, gastrointestinal, genitourinary, neurological, and/or musculoskeletal cases can be printed accurately when using any of the compatible 3D printers and materials.

Summary

All performance testing, which were conducted as a result of risk analyses and design impact assessments, showed conformity to pre-established specifications and acceptance criteria. The acceptance criteria were established in order to demonstrate device performance and substantial equivalence of the software to the predicate device.

9. CONCLUSIONS

Based on a comparison of the intended use and technological characteristics, the D2P software is substantially equivalent to the identified predicate device. Minor differences in technological and performance characteristics did not raise new or different questions of safety and effectiveness. Additionally, the non-clinical testing supports that the system performs in accordance with its intended use and is as safe, as effective, and performs as well as the predicate device.