DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

January 9, 2017

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

Re: K161841
Trade/Device Name: D2P
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: December 23, 2016
Received: December 27, 2016

Dear Ms. 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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161841

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 imaging information from a medical scanner such as a CT scanner to an output file. It is also intended as pre-operative software for surgical planning.
3D printed models generated from the output file are meant for visual, non-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.

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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: 3D Systems, Inc. (Simbionix)

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Official Contact: Kim Torluemke
Vice President, Quality and Regulatory, Healthcare

Date Prepared: January 5, 2017

3. DEVICE

Trade Name: D2P

Common Name: Image processing system and preoperative software for simulating /evaluating surgical treatment options.

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:

- Mimics, Materialise N.V (K073468)

5. DEVICE DESCRIPTION

The D2P software is a stand-alone modular software package that allows easy to use and quick digital 3D model preparation for printing or use by third party applications. The software is aimed at usage by medical staff, technicians, nurses, researchers or lab technicians that wish to create patient specific digital anatomical models for variety of uses such as training, education, and pre-operative surgical planning. The patient specific digital anatomical models may be further used as an input to a 3D printer to create physical models for visual, non-diagnostic use. 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

6. INDICATIONS FOR USE

The D2P software is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner such as a CT scanner to an output file. It is also intended as pre-operative software for surgical planning.

3D printed models generated from the output file are meant for visual, non-diagnostic use.

The Indications for Use statement for the D2P software is nearly identical to the predicate device. The subtle differences do not alter the intended clinical use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. 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 similar 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:

- The inputs to the subject device are equivalent to a subset of the inputs of the predicate device
- The outputs of the subject device are equivalent to a subset of the outputs of the predicate device

8. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a failure or latent flaw in the software could directly result in minor injury to the patient. Software verification and validation included:

- Verification of each independent software subsystem against defined requirements
- Verification of interfaces between software subsystems against defined interface requirements
- Validation of fully integrated system including all subsystems against overall system requirements.

Phantom Study

The purpose of the study was to evaluate, measure and compare the correlations between a physical phantom model with segmentations that were created using the subject and predicate device from a CT scan of the phantom model. Comparison between the physical phantom and both software systems revealed that all measurements fell within the set acceptance criteria.

Usability Study – System Measurements

The purpose of the study was to evaluate, measure and compare the inter and intra user variability between measurements taken by multiple users in the subject device. Comparison of the inter and intra user measurements showed that all measurements fell within the set acceptance criteria.

Usability Study – Segmentation

The purpose of the study was to visually and quantitatively compare segmentation models created by representative users. The comparison showed similarity in all models.

Segmentation Study

The purpose of the study was to visually and quantitatively compare segmentation models created by both the subject and predicate devices. The comparison showed similarity in all models.

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 characteristics did not raise new or different questions of safety and effectiveness. Additionally, the validation data supports that the system performs in accordance with its intended use and is substantially equivalent to the predicate device.