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

September 2, 2016

3DSystems, Simbionix Products
% Ms. Kim Torluemke
Vice President, Quality and Regulatory Affairs, Healthcare
3D Systems, Inc.
5381 South Alkire Circle
LITTLETON CO 80127

Re: K153705
Trade/Device Name: PROcedure Rehearsal Studio
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 12, 2016
Received: August 15, 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)*
K153705

Device Name
PROcedure Rehearsal Studio

Indications for Use *(Describe)*
The PROcedure Rehearsal Studio 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

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

[as required by section 807.92(c)]

PROcedure Rehearsal Studio™

510(k) Number K153705

1. SUBMITTER

Applicant's Name:
3DSystems, Simbionix Products
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kim.torluemke@3dsystems.com
Date Prepared:
December 22, 2015

2. DEVICE

Trade Name:
PROcedure Rehearsal Studio™

Common or Usual Name:
Radiological Image Processing System

Classification:
Name: System, Image Processing, Radiological
Product Code: LLZ
Regulation No: 892.2050
Class: 2
Classification Panel: Radiology

3. PREDICATE DEVICES

Main predicate:
PROcedure Rehearsal Studio™ cleared for marketing under K123269, K112387 and K093269

4. DEVICE DESCRIPTION

The PROcedure Rehearsal Studio software allows clinicians to create a patient specific 3D anatomical model based on a patient's CT for the purpose of preoperative surgical planning.

The 3D segmentation model produced by the PROcedure Rehearsal Studio may be exported to the Simbionix ANGIO Mentor Simulator Practice Environment and allow the physician to create a library of modules for training and post-operative debriefing. The ANGIO Mentor Simulator Practice Environment is not meant for clinical purposes and is intended to be used for training purposes only.

The modifications subject to this Special 510(k) submission are: (1) Graphic User Interface changes in various locations; (2) functional change in various locations which enable the addition of a Neuro module that allows the software to create 3D models for neurological scans in addition to the thoracic (TEVAR), abdominal (EVAR) and Carotid options that were previously cleared.

The Neuro module builds upon the previously cleared PROcedure Rehearsal Studio modules by adding the support for segmentation of the cerebral circulation system in addition to existing carotid, thoracic, and abdominal anatomies.

5. INDICATIONS FOR USE

The PROcedure Rehearsal Studio 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.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The software uses the same imaging inputs and substantially equivalent segmentation methods as the predicate device to create a 3D model which can be used for pre-operative surgical planning.

7. PERFORMANCE DATA

Below is a list of the tests that have been performed and successfully completed for the PROcedure Rehearsal Studio.

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 testing activities were conducted according to the following phases of the user work flow: Importing Patient Data, Segmentation and Centerlines. Verification was performed using four patients' datasets (Dataset A through Dataset D). Dataset A was of Carotid Type, Dataset B was of EVAR type, Dataset C was of TEVAR type and Dataset D was of Neuro Intervention type.

In addition to the verification testing above, the following tests were completed:

- Segmentation quality testing
- Phantom testing
- Usability testing

All the verification and validation tests passed successfully.

8. CONCLUSION:

The PROcedure Rehearsal Studio has the same intended use and technological characteristics as the previously cleared version of the same device (K123269, K112387 and K093269). Consequently, it is clear that the PROcedure Rehearsal Studio is as safe and effective as its predicate devices without raising any new safety and/or effectiveness concerns. Any differences have been addressed by extensive testing and validations and therefore negate any safety or effectiveness concerns.