Lazarus, 3D, Inc.
% Elisa Maldonado-Holmertz
RA/QA Consultant
Obelix Consulting
12416 Fairfax Ridge Place
AUSTIN TX 78738

July 8, 2021

Re: K201835
Trade/Device Name: PRE-SURE
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 29, 2021
Received: June 2, 2021

Dear Elisa Maldonado-Holmertz:

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

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

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)*
K201835

Device Name

PRE-SURE

Indications for Use *(Describe)*

The PRE-SURE software system 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 genitourinary 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.

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

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Operate with confidence

Section 005 - 510(k) Summary

1. INTRODUCTION

This document contains the 510(k) summary for the PRE-SURE device. The content of this summary is based on the requirements of 21 CFR 807.92.

2. SUBMISSION SPONSOR

Name: Lazarus 3D, Inc.

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Corvallis, OR 97330

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Submission Correspondent
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Contact Name: Elisa Maldonado-Holmertz
Contact Email: elisamh@obelixconsult.com

Date Prepared: 7 July 2021

Device Identification

Type of 510(k) Submission: Traditional

Trade Name: PRE-SURE

Common Name: System, Image Processing, Radiological

Regulation Description: Medical Image Management and Processing System

Regulation Number: 21 CFR 892.2050

Product Code: LLZ

Class of Device: II

Review Panel: Radiology

Reason for Submission: New device

Prior Related Submissions: None

Multiple Devices: None

3. LEGALLY MARKETED PREDICATE DEVICE

The PREoperateive SUrgical REhearsal (PRE-SURE) device is claimed to be substantially equivalent to the following legally marketed device:

- D2P, 3D Systems, Inc. (K183489).

No reference devices were used in this submission.

4. DEVICE DESCRIPTION

End Users of the PRE-SURE device receive digital and/or physical patient anatomical models from Lazarus 3D. The physical models are intended for adjunctive use along with other diagnostic tools and expert clinical judgement for diagnosis, patient management, and/or treatment selection of genitourinary applications. Digital models may be viewed by End Users using any program cleared for their intended use.

The PRE-SURE patient modeling system is a method for the creation of patient models. This system will be used exclusively by Lazarus 3D, with some physician input and feedback, to produce models for End Users. Importantly, and unlike other 3D modeling systems, in the PRE-SURE process the design and production of patient models is performed by Lazarus 3D and not by the End User or a third party. The internal process within Lazarus 3D used for creating PRE-SURE patient models includes use of an FDA cleared stand-alone software package. As a part of the PRE-SURE production process, this software is intended for internal use within Lazarus 3D to create digital anatomical models from patient radiological data that can be used by End Users for a 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 printing-based production process performed by Lazarus 3D to create physical patient models. Each individual patient's model can be created rapidly from the patient's radiological data using Lazarus 3D's patented rapid prototyping technology. The resulting physical models of patient anatomy are primarily composed of silicone materials that can be cut, can be sutured, and in some cases can even bleed.

5. INDICATIONS FOR USE

The PRE-SURE software system 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 genitourinary applications.

6. SUBSTANTIAL EQUIVALENCE DISCUSSION

PRE-SURE employs similar fundamental technologies as the identified predicate device, 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.
- Use of the 3D object for diagnosis, patient management and/or treatment selection.

However, in the PRE-SURE process the analysis of patient data and production of patient models is performed by Lazarus 3D and is provided as a service to End Users. By contrast, the predicate device is sold as a software and hardware package that allows End Users or third parties to produce their own patient models. Additionally, while the predicate patient models are produced in relatively hard materials (e.g., plastics), PRE-SURE physical models can be created in soft silicone materials that can be cut, sutured, and in some cases even bleed. Both devices can be used to create a physical rendering of radiological data for visualization and analysis. However, the additional capabilities of PRE-SURE models may provide new opportunities for pre-surgical planning and rehearsal.

Comparison to Legally Marketed Device:

Table 12A – Device Comparison Chart: Similarities and Differences

Manufacturer	**Subject Device** **Lazarus 3d, Inc.**	**Predicate Device** **3D Systems, Inc.**	**Significant Differences**
Trade Name	PRE-SURE	D2P	None
510(k) Number	K201835	K183489	
Product Code	LLZ	LLZ	None
Regulation Number	892.2050	892.2050	None
Regulation Name	Medical Image Management and Processing System	Medical Image Management and Processing System	None
Common Name	System, Image Processing, Radiological	System, Image Processing, Radiological	None
Indications for Use	The PRE-SURE 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	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	Nearly identical, except the subject device is only intended for use in genitourinary applications, while the predicate device is intended for use in cardiovascular, craniofacial, gastrointestinal, genitourinary, neurological, and/or musculoskeletal applications.

Manufacturer	Subject Device Lazarus 3d, Inc.	Predicate Device 3D Systems, Inc.	Significant Differences
Trade Name	PRE-SURE	D2P	None
	other diagnostic tools and expert clinical judgement for diagnosis, patient management, and/or treatment selection of genitourinary applications.	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.	
Material	Non-hazardous silicones, resins, and food products	Plastics	All components of PRE-SURE models are certified non-hazardous by OSHA 29 CFR 1910.1200.
Sterile	No	No	None

7. NON-CLINICAL PERFORMANCE DATA

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

Production Process Accuracy Study

The purpose of this accuracy study was to evaluate the accuracy of PRE-SURE patient model production processes. Models of various dimensions were created using PRE-SURE from computer models with dimensions pre-defined *in silico*. Comparisons were made between the physical models created using PRE-SURE and the *in-silico* input data, revealing that measurements fell within pre-defined acceptance criteria.

Digital and Physical Model Accuracy Study

The purpose of this accuracy study was to compare results from the entire PRE-SURE workflow to those of the predicate device. MRI and CT scan input data from actual cases were analyzed using the predicate and subject devices to create 3D computer models and

physical models of the patient anatomy. These models were then compared, revealing that measurements fell within pre-defined acceptance criteria.

Build Envelope Testing - Accuracy Validation

The purpose of this study is to define where on the 3D printer, and in what orientation, models can be produced in sufficient accuracy for the intended use. Models of genitourinary conditions were built using 3D prints from different locations the 3D printer build plate, and in different orientations. Results show that sufficient accuracy can be achieved for models built in any orientation or position.

Materials Testing – Accuracy Validation

The purpose of this study is to test the accuracy and bonding of the range of materials included in the build envelope for PRE-SURE physical patient models. Multi-material genitourinary models were produced using combinations of the most difficult to use materials within the PRE-SURE build envelope. Testing shows that all materials and material combinations produce models of sufficient accuracy for the intended use. Additionally, all tested materials bond well with all other tested materials and thus can be used together to form multi-material patient models.

Testing on Especially Challenging Genitourinary Cases

The purpose of this study is to test was to test the accuracy of the subject production process when creating complex genitourinary models. Models of three conditions that are difficult to produce for a variety of reasons were manufactured. These physical models were analyzed using a CT scanner and volumetrically compared against the digital design. Results indicate that the subject 3D manufacturing process can reproduce complex genitourinary conditions with sufficient accuracy for the intended use.

Summary

All performance testing which was 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 the device performance and substantial equivalence to the predicate device.

8. STATEMENT OF SUBSTANTIAL EQUIVALENCE

Based on a comparison of the intended use and technological characteristics, the PRE-SURE device 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.