Lazarus 3D
% Elisa Maldonado-Holmertz
RA Consultant
Obelix Consulting, LLC
806 JEFFERSON ST.
BASTROP TX 78602

May 26, 2023

Re: K230044
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 2, 2023
Received: May 4, 2023

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Imaging Devices
and Electronic Products
OHT8: Office of 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)*
K230044

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 judgment for diagnosis, patient management, and/or treatment selection of genitourinary, cardiovascular, neurological, respiratory, musculoskeletal, gastrointestinal, craniofacial, and pediatric 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 005 - 510(k) Summary

K230044

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.

SUBMISSION SPONSOR

Name: Lazarus 3D, Inc.

Address: 421 Water Ave. NE.
Albany, OR 97321

Phone: (541) 760 1805

Contact Name: Dr. Smriti Zaneveld
Contact Email: Smriti@laz3D.com

Additional Contact: Dr. Jacques Zaneveld
Additional Email: Zaneveld@laz3D.com

Submission Correspondent
Name: Obelix Consulting, LLC

Address: 806 Jefferson St.
Bastrop, TX 78602

Phone: (512) 431 6069

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

Date Prepared:11/28/2022

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: K201835

Multiple Devices: None

1. **LEGALLY MARKETED PREDICATE DEVICE**
   The Preoperative Surgical Rehearsal (Pre-Sure) device is claimed to be substantially equivalent to the following legally marketed device:

   - Pre-Sure, Lazarus 3D, Inc. (K201835).

2. **DEVICE DESCRIPTION**
   The Pre-Sure patient modeling system is a method for the creation of patient models. Importantly, and unlike other 3D modeling systems, in the Pre-Sure process the design and production of patient models is performed by Lazarus 3D or its affiliates (with physician input), and not by the End User. The Pre-Sure software process is FDA cleared for the analysis of patient radiological data to create a digital patient design, referred to as a "Digital Twin". Digital Twins can be used by End Users, when viewed in an appropriately cleared viewing program, for a variety of uses including training, education, and surgical planning.

   Patient specific Digital Twins may be further used as an input to a 3D printing-based production process performed by Lazarus 3D. This process creates physical patient models,

referred to as Pre-Sure models. Each individual patient's model can be created rapidly from the patient's radiological data. 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, and of hard plastic materials that can be sawed, drilled, and can accept screws.

End Users of the Preoperative Surgical Rehearsal (Pre-Sure) device receive digital and/or physical patient anatomical models from Lazarus 3D. Digital models may be viewed by End Users using any program cleared for their intended use. The physical models are intended for adjunctive use along with other diagnostic tools and expert clinical judgment for diagnosis, patient management, and/or treatment selection for genitourinary, cardiovascular, craniofacial, gastrointestinal, neurological, musculoskeletal, respiratory, and pediatric applications.

3. 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 judgment for diagnosis, patient management, and/or treatment selection of genitourinary, cardiovascular, neurological, respiratory, musculoskeletal, gastrointestinal, craniofacial and pediatric applications.

4. SUBSTANTIAL EQUIVALENCE DISCUSSION

Pre-Sure employs identical fundamental technologies as the identified predicate device (which is an earlier version of Pre-Sure technology). These fundamental technologies include:

- Viewing of medical imaging data in the axial, coronal, and sagittal views.
- Ability to process, review and analyze medical imaging data
- Seamless production of a physical model of the patient's anatomy from the digital design.
- Use of the physical model by the end-user for diagnosis, patient management and/or treatment selection.
- Opportunity to use the physical model for surgical rehearsals.

Two changes are included in the subject device. First, the subject version of Pre-Sure may use both silicone materials and hard plastic materials in models, while plastic materials were not used in predicate models. Second, while the predicate was only cleared for genitourinary applications, the subject device may be used for cardiovascular, neurological, respiratory, musculoskeletal, gastrointestinal, craniofacial and pediatric applications. Rigorous testing and investigation indicate that the present device has similar performance, intended use, and nearly identical technological characteristics as the predicate device, and raises no new questions regarding its safety or efficacy.

Comparison to Legally Marketed Device:

Table 12A – Device Comparison Chart: Similarities and Differences

Manufacturer	**Subject Device Lazarus 3d, Inc.**	**Predicate Device Lazarus 3d, Inc.**	**Significant Differences**
Trade Name	Pre-Sure	Pre-Sure	None
510(k) Number	-	K201835	-
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 and other diagnostic tools and expert clinical judgment	The Pre-Sure software is intended for use as a software interface and image segmentation system for transferring 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 judgment for diagnosis, patient management, and/or	Nearly identical, except the subject device is only intended for use in genitourinary applications, while the predicate device is intended for use in cardiovascular, neurological, respiratory, musculoskeletal, gastrointestinal, craniofacial and pediatric applications.

	for diagnosis, patient management, and/or treatment selection of cardiovascular, neurological, respiratory, musculoskeletal, gastrointestinal, craniofacial and pediatric applications.	treatment selection of genitourinary applications.	
Material	Non-hazardous silicones, non-hazardous plastic composites, resins, and food products	Non-hazardous silicones, resins, and food products	All components of Pre-Sure models are certified non-hazardous by OSHA 29 CFR 1910.1200.
Sterile	No	No	None

5. 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 predefined 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 predefined 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 to be built in any orientation or position on the 3D printer.

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 models were produced for genitourinary conditions 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 the accuracy of the subject production process when creating complex models for genitourinary applications. Multiple replicates were produced for several different genitourinary conditions. Designs were selected for difficulty, with highly complex designs being used for testing. The resulting physical models were analyzed using a CT scanner and volumetrically compared against the digital design. Results indicate that the Pre-Sure 3D manufacturing can reproduce complex genitourinary conditions with sufficient accuracy for the intended use.

Testing on Especially Challenging Cardiovascular Cases

The purpose of this study is to test the accuracy of the subject production process when creating complex models for cardiovascular applications. Multiple replicates were produced for several different cardiovascular conditions. Designs were selected for difficulty, with highly complex designs being used for testing. The resulting physical models were analyzed using a CT scanner and volumetrically compared against the digital design. Results indicate that the Pre-Sure 3D manufacturing can reproduce complex cardiovascular conditions with sufficient accuracy for the intended use.

Testing on Especially Challenging Neurological Cases

The purpose of this study is to test the accuracy of the subject production process when creating complex models for neurological applications. Multiple replicates were produced for several different neurological conditions. Designs were selected for difficulty, with highly complex designs being used for testing. The resulting physical models were analyzed using a CT scanner and volumetrically compared against the digital design. Results indicate

that the Pre-Sure 3D manufacturing can reproduce complex neurological conditions with sufficient accuracy for the intended use.

Testing on Especially Challenging Respiratory Cases

The purpose of this study is to test the accuracy of the subject production process when creating complex models for respiratory applications. Multiple replicates were produced for several different respiratory conditions. Designs were selected for difficulty, with highly complex designs being used for testing. The resulting physical models were analyzed using a CT scanner and volumetrically compared against the digital design. Results indicate that the Pre-Sure 3D manufacturing can reproduce complex respiratory conditions with sufficient accuracy for the intended use.

Testing on Especially Challenging Musculoskeletal Cases

The purpose of this study is to test the accuracy of the subject production process when creating complex musculoskeletal models. Multiple replicates of models for several different musculoskeletal 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 Pre-Sure 3D manufacturing can reproduce complex musculoskeletal conditions with sufficient accuracy for the intended use.

Testing on Especially Challenging Gastrointestinal Cases

The purpose of this study is to test the accuracy of the subject production process when creating complex gastrointestinal models. Multiple replicates of models for several different gastrointestinal 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 Pre-Sure 3D manufacturing can reproduce complex gastrointestinal conditions with sufficient accuracy for the intended use.

Testing on Especially Challenging Craniofacial Cases

The purpose of this study is to test the accuracy of the subject production process when creating complex craniofacial models. Multiple replicates of models for several different craniofacial 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 Pre-Sure 3D manufacturing can reproduce complex craniofacial conditions with sufficient accuracy for the intended use.

Testing on Especially Challenging Pediatric Cases

The purpose of this study is to test the accuracy of the subject production process when creating complex pediatric models. Multiple replicates of models for several different pediatric 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 Pre-Sure 3D manufacturing can reproduce complex pediatric conditions with sufficient accuracy for the intended use.

Testing on Hard and Soft Pre-Sure Material Bonding

The purpose of this study is to test if the bonding of hard and soft materials used in combination in Pre-Sure models is sufficient for them to maintain their integrity and accuracy during shipping and when used as intended. Many models with worst case designs and materials were subjected to a force in the worst case direction and orientation. Models were then measured to determine if they were damaged as a result of the force applied. Results indicate that the Pre-Sure models containing both hard and soft materials are sufficiently robust to maintain their integrity and accuracy during shipping and when used as intended.

Summary

All performance testing which was conducted as a result of risk analysis 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.

6. 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 and scope 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.