RTsafe, Inc.
℅ Jennifer Palinchik
President
JALEX Medical, LLC.
30311 Clemens Rd. Suite #5D
WESTLAKE OH 44145

July 10, 2018

Re: K180697
Trade/Device Name: Personalized PseudoPatient™ PV
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: June 15, 2018
Received: June 18, 2018

Dear Ms. Palinchik:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

Robert A. 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)*
K180697

Device Name
Personalized PseudoPatient™ PV

Indications for Use *(Describe)*
The Personalized PseudoPatient™ PV is intended for the quality assurance of patient specific brain treatments done prior to and/or interfractionally to delivery by external beam radiotherapy, including IMRT and VMAT. It is also intended for quality assurance of the radiation delivery system.

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

Submitted By: RTsafe, Inc.
342 Regent Circle
San Antonio, TX 78231

Date: 06/27/2018

Contact Person: Jennifer Palinchik, President
Contact Telephone: (440) 541-0060
Contact Fax: (440) 933-7839

Device Trade Name: Personalized PseudoPatient™ PV
Device Classification Name: Accessory – Linear Accelerator (21 CFR 892.5050)
Device Classification: Class II
Reviewing Panel: Radiology
Product Code: IYE
Primary Predicate Device: ScandiDos AB Delta4 Phantom (K151426) This device has not been subject to any recalls.

Device Description:

The Personalized PseudoPatient™ PV is a precise model of a patient's CT-scan. Bone structure and external contour are 3D printed using bone equivalent material. The PseudoPatient™ is a pre-treatment end-to-end verification device. The device verifies the TPS dose calculations as well as the following parts of the treatment chain: patient set-up, patient immobilization, image guidance, and treatment delivery. The 3D printed, Personalized PseudoPatient™ PV is loaded with one of the following available types of dosimeters: ion chamber (IC) insert (or any kind of insert for point dosimetry), and/or film insert (FL). The insertcan be relocated depending on demands of treatment. The ion chamber inserts are specifically designed for the detector type indicated by the end user and constructed of Poly(methyl methacrylate) (PMMA). The PseudoPatient™ FL is equipped with a Real Water (RW3) insert to accommodate a dosimetry film (filled with water by the end-user).

Intended Use:

The Personalized PseudoPatient™ PV is intended for the quality assurance of patient specific brain treatments done prior to and/or interfractionally to delivery by external beam radiotherapy, including IMRT and VMAT. It is also intended for quality assurance of the radiation delivery system.

Summary of Technological Characteristics:

The Personalized PseudoPatient™ PV and predicate have the same intended use. Both devices compare similarly in:

- Ease of alignment for positioning
- Accurate dose verification and absolute measurement
- Compatibility with any treatment planning systems (TPS)
- Patient quality assurance and machine quality assurance capabilities
- Design features which allow the insertion of third party dosimeters that measure the placement and intensity of radiation treatment
- Tissue and bone equivalent materials that allow the radiation to transfer to the dosimeters
- Overall size of cylinder to average patient anatomy
- Dosimeter usage
- Same intended use
- Biocompatibility (non-patient contacting)
- Sterility (non-sterile)

Clinical and Non-clinical Testing:

Clinical testing is not necessary for this device type. This technology is well known and used in the field of dosimetry in radiation therapy. Validation of the calculated absolute dose and dose distribution using the device proved to be clinically acceptable.

The device is non-patient contacting and provided non-sterile, therefore, biocompatibility testing and sterility testing is not required.

Verification testing of the final device is performed for each unit produced to confirm accuracy of the printer and accuracy of the finished device to the patient anatomy. The basic specification is that the phantom is anatomically accurate and mimics the patient's morphological characteristics. A structure with known dimensions is printed simultaneously with the phantom. These dimensions are digitally and physically compared using validated software and calibrated equipment to ensure the finished device meets required specifications.

Verification testing is performed for each lot of material used for the finished device. This testing confirms the material is equivalent to bone by measuring the Hounsfield units of a 3D printed structure.

Conclusion:

Based on the intended use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence and does not raise additional questions of safety or effectiveness.