Radialis Inc.
% Eileen Heller
Final Reviewer
BeanStock Ventures
8885 Rio San Diego Dr. #237
SAN DIEGO CA 92108

February 4, 2022

Re: K214062
Trade/Device Name: Radialis PET Camera
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS
Dated: December 23, 2021
Received: December 27, 2021

Dear Eileen Heller:

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)*
K214062

Device Name
Radialis PET Camera

Indications for Use *(Describe)*
The Radialis PET Camera is intended for medical purposes to image and measure the distribution of injected positron emitting radiopharmaceuticals in human beings for the purpose of determining various metabolic and physiologic functions within the human body.

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.

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510(k) SUMMARY

Radialis PET Camera K214062

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Radialis Inc.
Suite 2300B, 290 Munro Street
Thunder Bay, Ontario
P7A 7T1
Canada

Phone: 1-800-601-3177
Contact Person: Michael Waterston

Date Prepared:2021-07-25

Name of Device

Radialis PET Camera

Device Classification and Product Code

Emission computed tomography system, 21 CFR 892.1200, Class II, KPS

Predicate Devices

Naviscan PEMFlex Solo II High Resolution PET Scanner (K090553, Predicate Device)

Indications for Use

The Radialis PET Camera is intended for medical purposes to image and measure the distribution of injected positron emitting radiopharmaceuticals in human beings for the purpose of determining various metabolic and physiologic functions within the human body.

Device Description

The Radialis PET Camera is a high spatial resolution, small field-of-view PET imaging camera specifically developed for close-range, organ-targeted (i.e., limited field) imaging. The Radialis PET Camera is a partial-ring planar PET camera, equipped with lutetium-containing gamma-ray detectors, which collect gamma rays emitted by injected positron-emitting radiopharmaceuticals, and generates images corresponding to the relative concentrations of these radiopharmaceuticals in the body. The Radialis PET Camera is designed to collect gamma rays emitted by the injected radiopharmaceutical in a patient's body part with high efficiency.

Standards Compliance

The Radialis PET Camera has been tested and found to be in compliance with the following standards:

- ANSI AAMI ES60601-1:2005(R)2012 and A1:2012, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety And Essential Performance
- ANSI AAMI IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety And Essential Performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- NEMA NU 4:2008 Performance Measurements of Small Animal Positron Emission Tomographs

Summary of Non-Clinical Testing

Biocompatibility	The patient contact material in the Radialis PET Camera was tested for biocompatibility in accordance with applicable standards.
Electrical Safety / Electromagnetic Compatibility Testing	The Radialis PET Camera has undergone electrical safety testing per AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, and electromagnetic compatibility (EMC) testing per IEC 60601-1-2:2014.
Performance Testing	Functional testing and software validation to design input requirements was completed, including testing for: - Radiation - Resolution - Spatial Linearity - System Sensitivity - Flood Field Uniformity - Coincidence - Scatter - Imaging Workflow - Notifications - Cleaning - Lifecycle
Software Testing	Software for the Radialis PET Camera was designed and developed according to a robust software development process, and was rigorously verified and validated, in accordance with IEC 62304 Medical Device Software - Software Life Cycle Processes and the Guidance For The Content Of Premarket Submissions For Software Contained In Medical Devices - Guidance For Industry And FDA Staff.

Clinical Images	Three (3) patients were imaged with the Radialis PET Camera and the images were provided. The images demonstrate the high-resolution image capability of the Radialis PET Camera.

Test results show that the Radialis PET Camera complies with its predetermined specifications and with applicable standards.

Substantial Equivalence

The subject device, Radialis PET Camera, is substantially equivalent to the legally marketed predicate device, Naviscan PEMFlex Solo II (K090553). The Radialis PET Camera has the same intended use and indications for use as its predicate device, as well as similar technological characteristics and principles of operation to its predicate device.

Bench testing results also demonstrate that the Radialis PET Camera is substantially equivalent to the predicate device.

Conclusions

The Radialis PET Camera has the same intended use as its predicate device. Any minor differences in the technological characteristics do not raise any new or different questions of safety or effectiveness. Bench testing to FDA-recognized standards has demonstrated the safety and effectiveness of the Radialis PET Camera with regards to differences in technological characteristics. Therefore, the Radialis PET Camera is substantially equivalent to the Naviscan PEMFlex Solo II.