May 24, 2024

Shimadzu Corporation Medical Systems Division
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
Naples, Florida 34114

Re: K240827
Trade/Device Name: Set-5002
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS
Dated: March 12, 2024
Received: March 26, 2024

Dear Daniel Kamm:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Daniel M. Krainak, Ph.D.
Assistant Director
DHT8C: Division of Radiological Imaging
and Radiation Therapy Devices
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)*
K240827

Device Name
SET-5002

Indications for Use *(Describe)*

The equipment is intended to obtain positron emission tomography (PET) images of parts of the human body that fit in the patient aperture (e.g. head or breast) to detect abnormal pattern of distribution of radioactivity after injection of a positron emitting radiopharmaceutical. This information can assist in diagnosis, therapeutic planning and therapeutic outcome assessment.

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.

510(k) Summary K240827

SHIMADZU CORP.
1, Nishinokyo-Kuwabaracho, Nakagyo-ku,
Kyoto City, JAPAN 604-8511
Date submitted: May 24, 2024
Prepared by: Koichi Kataoka, General Manager,
Quality Assurance Department, Medical Systems Division

1. **Identification of the Device:**
   Trade/Device Name: SET-5002
   Regulation Number: 21 CFR 892.1200
   Regulation Name: Emission computed tomography system
   Regulatory Class: Class II
   Product Code: KPS

2. **Equivalent legally marketed device: K210450**
   Trade/Device Name: BBX-PET Scanner
   Regulation Number: 21 CFR 892.1200
   Regulation Name: Emission computed tomography system
   Regulatory Class: Class II
   Product Code: KPS

3. **Purpose of Submission: New but Substantially Equivalent Device.**

4. **Device Description: The SET-5002 PET scanner is designed to image the patient's breast or head which is placed in the aperture provided. The scanner can be easily switched from head to breast mode and back again with the push of a button on the control panel:**

Breast Mode **Head Mode**

This is the operating principle: When positrons are emitted from the radioactive drug administered to the patient, they annihilate electrons in body tissue. That process emits two annihilation photons (hereinafter "gamma rays") with an energy of 511 keV in the 180-degree direction. The PET System collects data by simultaneously counting both of these gamma rays using detectors arranged in a circular configuration. After collecting data for the specified scan time, an image is then reconstructed from that

data based on the quantitative distribution of the radioactive drug. The following corrections are necessary for obtaining a quantitative distribution image: Normalization, Attenuation Correction, Scatter Correction, Random Correction, Decay Correction, Standard Time Correction, Count Losses Correction, and Cross Calibration. Operation of the system requires trained persons. The system is designed to be operated in a controlled medical environment such as a hospital or clinic. The unit is supplied with a computer which acquires and stores patient images. The scintillator type is Lutetium. The detectors are SiPM (Silicon photomultipliers).

5. **Indications for Use: The equipment is intended to obtain positron emission tomography (PET) images of parts of the human body that fit in the patient aperture (e.g. head or breast) to detect abnormal pattern of distribution of radioactivity after injection of a positron emitting radiopharmaceutical. This information can assist in diagnosis, therapeutic planning and therapeutic outcome assessment.**

6. **Comparison of Technological Characteristics with the predicate device:**

ITEM	Predicate Device K210450 BBX Pet	SET-5002
Indications for Use	BBX™-PET scanner is intended to obtain positron emission tomography (PET) images of parts of the human body that fit in the patient aperture (e.g., head) to detect abnormal pattern of distribution of radioactivity after injection of a positron emitting radiopharmaceutical. This information can assist in research, diagnosis, therapeutic planning and therapeutic outcome assessment.	The equipment is intended to obtain positron emission tomography (PET) images of parts of the human body that fit in the patient aperture (e.g. head or breast) to detect abnormal pattern of distribution of radioactivity after injection of a positron emitting radiopharmaceutical. This information can assist in diagnosis, therapeutic planning and therapeutic outcome assessment. SAME
Imaging section of the body parts	Head only	Head and breast only
Detector Module	Detector module consists of Lutetium Fine Silicate crystals (LFS) optically coupled to solid state silicon photomultiplier. The size of crystal is 1.76 (X) × 1.76 (Y).	Detector module consists of Lutetium included crystals (e.g. LGSO) optically coupled to solid state silicon photomultiplier. The width of crystal is 2.1 (X) × 2.1 (Y).
Detector Arrangement	The detector modules are arranged in a cylindrical shape with an inner diameter of 29 cm and an axial length of 10 cm in the in-section direction.	The detector modules are arranged in a cylindrical shape with an inner diameter of 30 cm and an axial length of 16.2 cm in the in-section direction.
Bore/ Opening Size	28.8 CM	28.3 CM
Transaxial Field of View	250 mm	264 mm
Axial Field of View	100 mm	162 mm (SET-5002)

ITEM	Predicate Device K210450 BBX Pet	SET-5002
Principle of detection	The detectors detect two gamma rays almost simultaneously that are emitted oppositely from radioactivity inside the patient body. The detected informations such as timing, energy, and position of the crystal are formed as a coincidence events and recorded.	SAME
Data Corrections	Attenuation Correction Calculation based method from emission data. Scatter Correction Single scatter point based method. Dead-Time Correction Count-rate based method.	SAME
Resolution (Specification)	3 mm FWHM	2.5 mm FWHM (Better)
Performance Data	Resolution(@1cm) : 2.6mm FWHM Sensitivity (@0cm) : 3.7 cps/kBq NECR : 9.72 kcps@3.94 kBq/mL	Resolution(@1cm) : 2.4mm FWHM Sensitivity (@0cm) : 7.2 cps/kBq NECR : 35.8 kcps@5.9 kBq/mL
Power Source	AC Line	SAME

7. Performance Testing Information (Bench testing)
    a. Electrical Safety Testing was done in accordance with IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, FDA Recognition 19-49
    b. EMC Testing was done in accordance with IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard, FDA Recognition 19-36.
    c. Performance testing was done in compliance with NEMA Standards Publication NU 2-2018 Performance Measurements of Positron Emission Tomographs (PETS) FDA Recognition 12-326
    d. Performance testing was done according to the FDA Guidance Document: Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems

8. Clinical Performance Test: A clinical reader study using the SET-5002 was conducted at U.S. clinical site. The study included review by board certified radiologist to assess whether overall image quality of the SET-5002 demonstrated acceptable diagnostic results for brain and breast. The board-certified radiologist reviewed 12 brain images and 6 breast images, providing PET imaging findings related to the progression of dementia, tumor detection, and the extent of spread. The results of the reader study support the determination of substantial equivalence with predicate device. A reader attested that her

assessments of image quality of the SET-5002 demonstrated acceptable diagnostic results.

9. **Conclusion: The performance testing data supports the safety of the device and the validation testing demonstrate that new device should performs as intended in the specified use. Based on our risk analysis and bench testing, the differences do not affect its clinical safety or effectiveness. From the result of our risk analysis, software verification and validation, and testing discussed above, it is our conclusion that the SET-5002 device is substantially equivalent to the legally marketed predicate devices. Therefore, new device is as safe, as effective, and performs as well as or better than the predicate device.**