Prescient Imaging, LLC
% Mr. Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
WARREN NJ 07059

March 17, 2021

Re: 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
Dated: February 12, 2021
Received: February 16, 2021

Dear Mr. Yungvirt:

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)*
K210450

Device Name
BBX™ -PET Scanner

Indications for Use *(Describe)*

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.

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.

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SECTION 5- 510(K) SUMMARY

I. SUBMITTER INFORMATION

Submitter	Prescient Imaging LLC., 12569 Crenshaw Blvd Hawthorne, CA-90250
Contact Person	Farhad Daghighian, Ph.D. & Jeffrey Chou 12569 Crenshaw Blvd, Hawthorne CA-90250 Phone: (310) 428-4101 ceo@prescientimaging.com
Date	03/10/2020

II. DEVICE IDENTIFICATION

Trade/ Proprietary Name	BBX™-PET Scanner
Common Name	PET Scanner
Classification Name	Emission computed tomography system
21 CFR Reference	892.1200
Classification	Class II
Panel	Radiology
Product Code	KPS

III. IDENTIFICATION OF PREDICATE DEVICE

Predicate Device	NeuroPET 510(k) number: K091269 Applicant: PhotoDetection Systems, Inc.

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The BBX-PET Scanner is a Positron Emission Tomography (PET) system to image the distribution of injected positron emitting radiopharmaceuticals into live humans or animals. The BBX-PET Scanner produces images that represent the internal distribution of radioactivity in the head. The BBX-PET Scanner is comprised of two parts; the Gantry containing detectors and electronics, and the Universal Console that contains the computer workstation. These two parts are connected to each other using optical fiber and an USB cable. The detector assembly is composed of scintillation crystal Lutetium Fin-Silicate (LFS) and light detector photomultiplier. These detectors are arranged on the surface of a cylindrical shell with the diameter of 29 cm in the Gantry. Various electronic circuits are used to process and digitize the signals of these detectors and process the data and store in the computer of the Universal Console for image reconstructions and display.

V. 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, therapuetic planning and therapeutic outcome assessment.

Both the subject and predicate device have the same intended use for obtaining positron emission tomography (PET) images of parts of the human body that fit in its patient aperture. Also, their field of views are very similar and suitable for brain imaging.

The few minor differences between the BBX-PET and the predicate device do not alter the intended use of the device nor do they affect the safety and effectiveness of the BBX-PET relative to the predicate.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Both scanners are Positron Emission Tomography systems used to image and measure the distribution of injected positron emitting radiopharmaceuticals in human beings. The PET Scanners both produce images that represent the internal distribution of radioactivity in the head or other body parts that fit in the similar field of view. At a high level, the subject and predicate devices are based on the following same technological elements:

- The PET detectors are arranged on a cylindrical shell with inner diameter of 29 cm vs. 31 cm.
- The detectors detect gamma rays that are emitted by radioactivity placed inside this cylinder.
- The detectors consist of scintillators and photomultipliers.
- The detectors detect the gamma rays and the coincidence events are formed based on timing, energy and position of detection of the annihilation photons in the detectors.
- Software acquires, displays and transfers these images to a network server.
- Both PET scanners use calculated attenuation correction method.

The following technological differences exist between the subject and predicate devices:

- BBX-PET scintillators are lutetium fine-silicate (LFS), optically coupled to solid- state photomultipliers.
- The predicate device uses detectors consisting of blocks of 16x10 CsI(Na) scintillators, attached to photomultiplier tubes.

VII. PERFORMANCE DATA

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

i. Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the BBX™-PET scanner. The system complies with the IEC 60601-1: 2005 (Third Edition) + COOR.1:2006 + CORR.2:2007 + A1:2012 Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance

for electrical safety and the IEC 60601-1-2 ed 4.0 (2014-02) Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests for EMC.

ii. Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (CDRH, 2005)." The software for this device was considered as a "moderate" level of concern, since a malfunction or a latent design flaw might lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that might lead to minor injury.

iii. Performance Testing – Bench

Performance testing was conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff," Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems" Section IX.C.2. (CDRH, 1998).

Performance of the BBX™-PET Scanner has been tested by Prescient Imaging LLC according to NEMA NU-2:2012 - Performance Measurements of Positron Emission Tomography. The testing performed include:

1. SPATIAL RESOLUTION
2. SCATTER FRACTION, COUNT LOSSES, AND RANDOMS MEASUREMENT
3. SENSITIVITY
4. ACCURACY: CORRECTIONS FOR COUNT LOSSES AND RANDOMS
5. IMAGE QUALITY, ACCURACY OF CORRECTIONS

Test results indicate that BBX™- PET Scanner complies with its predetermined specification and the applicable standards.

iv. Performance Testing - Clinical Effectiveness

Clinical effectiveness was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff," Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems" Section IX.F. (CDRH, 1998).

Sample images from three clinical cases using the BBX™-PET Scanner were provided.

VIII. CONCLUSIONS

The data support the safety of the device and the hardware and software verification and validation demonstrate that the BBX™-PET Scanner should perform as intended in the specified use conditions. The sample images from three clinical cases supported the clinical effectiveness of the BBX™-PET Scanner. Based upon performance data, BBX^{TM}-PET Scanner is substantially equivalent to the predicate device.