August 15, 2025

Brightonix Imaging, Inc.
c/o Lee Strong
Medical Device Regulatory Consultant
510K FDA Inc.
156 E. Granada Blvd.
Ormond Beach, FL 32176

Re: K250170
Trade/Device Name: PHAROS
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: KPS
Dated: July 16, 2025
Received: July 16, 2025

Dear Lee Strong:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
Magnetic Resonance and Nuclear Medicine Team
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250170

Device Name
PHAROS

Indications for Use *(Describe)*
PHAROS is a dedicated PET scanner intended to obtain Positron Emission Tomography (PET) images of parts of human body that fit in the patient aperture (brain, breast, arms and legs) to detect abnormal patterns 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"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."

510(k) Summary
K250170 – PHAROS

August 13, 2025

1 Applicant

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Consultant

510K FDA Inc.
156 E. Granada Blvd
Ormond Beach, FL 32176

Phone: (386)846-6037
Contact: Lee Strong, (lee@510kfda.com)

2 Device Identification

Trade/Model Names:	PHAROS
Regulation Name:	Emission computed tomography system
Regulation Number:	21 CFR 892.1200
Primary Product Code:	KPS
Classification Name:	System, tomography, computed, emission
Regulatory Class:	Class II
510k Review Panel:	Radiology

3 Predicate Device

Predicate #:	K210450
Predicate Trade Name:	BBX-PET Scanner
Product Code:	KPS
Classification Name:	System, tomography, computed, emission
Regulation:	21 CFR 892.1200
Classification:	Class II
Panel:	Radiology

4 Device Description

PHAROS is a specialized high-sensitivity and high-resolution PET system designed for imaging specific organs, such as the brain, breast, arms and legs.

Positron emission tomography (PET) captures images by detecting the distribution of internal radioactivity in human organs, utilizing radioactive pharmaceuticals. This technology reconstructs the body's internal biochemical and metabolic processes, producing high-resolution 3D visualizations. The method involves measuring a pair of

simultaneous gamma rays, each with an energy of 511 keV, resulting from the annihilation of positrons. By labeling the positron emitter with a tracer and using a ring-shaped gamma ray detector, the spatial location of positron-emitting nuclides within the body is visualized.

PHAROS features four different scanning modes, each tailored for specific types of imaging:

1) Brain Scan Mode (Sitting Position):
This mode is designed for brain imaging while the patient is seated.
2) Brain Scan Mode (Lying Position):
This mode is designed for brain imaging while the patient lies down on a bed.
3) Breast Scan Mode:
This mode is designed for breast imaging while the patient lies in a prone position.
4) Periphery Scan Mode:
This mode is designed for imaging the periphery of the body, including the arms, hands, legs, and knees.

For both upper and lower extremity imaging, the height of detector head can be adjusted to ensure optimal patient comfort and accurate positioning. Aside from the physical height adjustment of the detector head, there is no difference in image acquisition method or image generation algorithm between upper and lower extremity scans.

5 Intended Use/Indications for Use

PHAROS is a dedicated PET scanner intended to obtain Positron Emission Tomography (PET) images of parts of human body that fit in the patient aperture (brain, breast, arms and legs) to detect abnormal patterns of distribution of radioactivity after injection of a positron emitting radiopharmaceutical. This information can assist in diagnosis, therapeutic planning and therapeutic outcome assessment.

Indications for Use Comparison

The subject device indications for use include examples of parts of human body that fit in the patient aperture (brain, breast, arms and legs).

6 Technological Comparison

Characteristic	Predicate Device	Subject Device	Comparison
Device name	BBX-PET Scanner	PHAROS	
Device Photograph			
510(k)	K210450	K250170	
Manufacturer	Prescient Imaging, LLC	Brightonix Imaging Inc.	
Product Code	KPS	KPS	Same as Predicate
Intended Use	Dedicated Positron Emission Tomography	Dedicated Positron Emission Tomography	Same as Predicate

Characteristic	Predicate Device	Subject Device	Comparison
Indications for Use	BBX-PET is a scanner 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 patterns of distribution of radioactivity after injection of a positron-emitting radiopharmaceutical. This information can assist in research, diagnosis, therapeutic planning, and therapeutic outcome assessment.	PHAROS is a dedicated PET scanner intended to obtain Positron Emission Tomography (PET) images of parts of human body that fit in the patient aperture (brain, breast, arms and legs) to detect abnormal patterns of distribution of radioactivity after injection of a positron emitting radiopharmaceutical. This information can assist in diagnosis, therapeutic planning and therapeutic outcome assessment.	Similar
Principle of detection	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.	PHAROS generates tomographic images that represent the internal distribution of radioactivity in the patient's head and brain, Extremity, Breast	Similar
Scintillator configuration / Scanner	Double-layer staggered Silicate Lutetium Fine pixelated crystals (13 x 13 and 14 x 14 arrays, 1.76-mm pitch) coupled to light detector solid state silicon photomultiplier. One hundred twenty-eight blocks positioned in a circular shape make up the gantry, with bore diameter of 288mm, and 250mm and 100mm transaxial and axial FoVs.	Pixelated lutetium-based scintillator coupled to silicon photomultipliers. A single detector module consists of 24 x 32 scintillators with 1.92 x 1.92 x 15 mm3. 2(B480D)/3(B720D)/4(B960D) rings of 20 detector modules positioned in circular shape. Bore diameter is 320 mm and useful FOV is 300 mm transaxial and 130/196/262 mm (B480D/B720D/B960D) axial depending on type.	Both use pixelated scintillation crystals coupled to silicon photomultipliers in circular shape. PHAROS uses single-layer crystal, but predicate device uses dual-layer crystal. PHAROS has bigger bore size and axial field-of-view. These differences do not affect the indications, only the performance.
Target population	Adults, young adults	Adults and adolescent	Same as Predicate
Anatomical site	Parts of the human body that fit in the patient aperture	Parts of the human body that fit in the patient aperture	Same as Predicate
Where used	Hospital	Hospital	Same as Predicate
Energy used and/or delivered	Detects distribution of radioactivity after injection of a positron emitting radiopharmaceutical. No energy delivered.	Detects distribution of radioactivity after injection of a positron emitting radiopharmaceutical. No Energy Delivered	Same as Predicate
Human factors	PET detection system in a movable cart. Its gantry can move up to allow brain imaging while the patient is seated. It can also move down to image the breast without compression, while a patient is lying on a biopsy table or rotate and	The PET detection system in a movable gantry and includes variable patient chair. Gantry and patient chair can be moved automatically to make various scan position. Gantry moves up to allow brain imaging while the patient is	Both systems can acquire images of brain, breast, hand and leg in lying and seated position.

Characteristic	Predicate Device	Subject Device	Comparison
	allow imaging the breast, hand, or leg in a seated position.	seated. And it can also move down to image the brain and breast in lying position and allow imaging the leg and knee in a seated position.	Main difference is that the variable patient chair is part of the system in PHAROS. The basic safety of the patient chair has been verified through the IEC60601-1 test, and the mechanical movement of the chair does not affect the image performance and effectiveness.
Design	The BBX-PET Scanner is comprised of two parts; the Gantry containing detectors and electronics, and the Universal Console that the computer contains workstation. These two parts are connected to each other using optical fiber and a USB cable.	PHAROS is comprised of three parts; the Main body containing detectors and electronics, variable gantry, patient chair; and the control box for communication between operator and patient and device control; workstation including software and performing data acquisition and reconstruction. Main body and workstation are connected though a dedicated optical cable. Main body, control box and workstation are also connected though a dedicated ethernet network. Workstation is connected to hospital's network with DICOM Worklist support and PACS connectivity.	Similar. PHAROS includes an additional control box for user convenience and the predicate device uses an extra USB cable. These differences do not affect the indications for use, safety or effectiveness.
Performance Data (Specifications)	Spatial resolution in FWHM at the center: 2.2mm Spatial resolution in FWHM at 10 cm: Not published Transverse resolution: 2.2mm Axial resolution: 2.2mm Energy resolution: Not Published System sensitivity: 1.1% Coincidence timing window: Not published Scatter fraction: Not published Scatter correction method: Not published Slice thickness: Depends on reconstruction (2mm/4mm) Count rate sensitivity: 10 cps/kBq	Spatial resolution in FWHM at the center: <2.3 mm Spatial resolution in FWHM at 10 cm: <3.5 mm Transverse resolution: <2.3 mm Axial resolution: <2.3 mm Energy resolution: < 18% System sensitivity: > 4% (B480D), > 5.5% (B720D), > 6.5% (B960D) Coincidence timing window: 3.2 ns Scatter fraction: < 35% Scatter correction method: tail-fitting / Single scatter simulation Slice thickness: Depends on reconstruction (1 mm / 2 mm) Count rate sensitivity: > 3 cps/kBq (B480D), > 7 cps/kBq (B720D),	Similar. PHAROS is equipped with Time-of-Flight (TOF) functionality, a feature not present in the predicate device. This does not alter the indications for use, safety or effectiveness.

Characteristic	Predicate Device	Subject Device	Comparison
	Isolation of the detector from background: Not applicable for PET Intrinsic spatial resolution: Not applicable for PET Attenuation: Calculated method Time-of-flight: Not applicable Computer: GPU	> 10 cps/kBq (B960D) Isolation of the detector from background: Not applicable for PET Intrinsic spatial resolution: Not applicable for PET Attenuation: Calculated method, Template-based method Time-of-flight: < 275 ps Computer: GPU	
Materials and biocompatibility	Standard electronics and medical grade materials	Standard electronic and medical grade materials	Same as Predicate
Compatibility with the environment and other devices	Complies with standard IEC 60601-1-2 ed 4.0 (2014-02) Medical equipment electrical Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances - Requirements and tests for EMC.	Complies with standard IEC 60601- 1-2:2014/A1:2020. Medical electrical equipment – Part 1−2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility Requirements and tests for EMC.	Same as Predicate
Sterility	The product is not sterile and has not to be sterilized by the user. Cleaning procedure devices. Cleaning of standard medical devices	The product is not sterile and has not to be sterilized by the user. Cleaning procedure devices. Cleaning of standard medical devices	Same as Predicate
Mechanical and electrical safety	Complies with standard IEC (Third 60601-:2005 Edition) + COOR.1:2006 + CORR.2:2007 + A1:2012 Medical equipment electrical Part 1: General requirements for basic safety and essential performance for electrical safety	Complies with standard ANSI/AAMI ES60601-1:2005/A2:2021. Medical electrical equipment – Part 1: General requirements for basic safety and essential performance	Same as Predicate
Clinical effectiveness	3 clinical images are provided from Prescient BBX-PET to demonstrate the image capability and the fulfillment with its predetermined specification.	5 clinical images are provided from PHAROS to demonstrate the image capability and the fulfillment with its predetermined specification.	Similar

7 Performance Data

7.1 Electrical safety and electromagnetic compatibility (EMC)

The device passed these tests to the standards IEC 60601-1 and IEC 60601-1-2.

7.2 Performance Testing – Bench

The device conforms to all applicable portions of "Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems", document issued on: December 3, 1998.

The device was evaluated in accordance with the NEMA NU2:2018 and NEMA NU4:2008 standards.

<table>
<tr><th>Item</th><th>Pass/Fail Criteria</th><th>Data Analysis and Result</th><th>Result</th></tr>
<tr><td>Spatial resolution</td><td>Spatial resolution
< 2.3 mm @ 1 cm offset</td><td><table><tr><th>Type</th><th>B480D-X</th><th>B720D-X</th><th>B960D-X</th></tr><tr><td>Spatial resolution @ 1 cm</td><td>2.23 mm</td><td>2.21 mm</td><td>2.09 mm</td></tr><tr><td>Spatial resolution @ 10 cm</td><td>3.34 mm</td><td>3.23 mm</td><td>3.32 mm</td></tr></table></td><td>Pass</td></tr>
<tr><td>Scatter fraction @ peak NECR</td><td>Scatter fraction
< 35% for all type</td><td><table><tr><th>B480D-X</th><th>B720D-X</th><th>B960D-X</th></tr><tr><td>25.93%</td><td>26.43%</td><td>27.12%</td></tr></table></td><td>Pass</td></tr>
<tr><td>Peak NECR</td><td>Peak NECR<table><tr><th>B480D-X</th><th>B720D-X</th><th>B960D-X</th></tr><tr><td>> 30 kcps</td><td>> 60 kcps</td><td>> 90 kcps</td></tr></table></td><td><table><tr><th>B480D-X</th><th>B720D-X</th><th>B960D-X</th></tr><tr><td>33.9 kcps</td><td>71.1 kcps</td><td>109.9 kcps</td></tr></table></td><td>Pass</td></tr>
<tr><td>Sensitivity</td><td><table><tr><th>B480D-X</th><th>B720D-X</th><th>B960D-X</th></tr><tr><td>> 3 cps/kBq</td><td>> 7 cps/kBq</td><td>> 10 cps/kBq</td></tr></table></td><td><table><tr><th>B480D-X</th><th>B720D-X</th><th>B960D-X</th></tr><tr><td>3.46 cps/kBq</td><td>7.61 cps/kBq</td><td>13.3 cps/kBq</td></tr></table></td><td>Pass</td></tr>
<tr><td>Energy resolution</td><td>Energy resolution < 18%</td><td><table><tr><th>B480D-X</th><th>B720D-X</th><th>B960D-X</th></tr><tr><td>13.2%</td><td>13.8%</td><td>13.4%</td></tr></table></td><td>Pass</td></tr>
<tr><td>Time resolution</td><td>Time resolution < 275 ps</td><td><table><tr><th>B480D-X</th><th>B720D-X</th><th>B960D-X</th></tr><tr><td>249 ps</td><td>245 ps</td><td>247 ps</td></tr></table></td><td>Pass</td></tr>
</table>

7.3 Clinical Evaluation Summary & Conclusions

To evaluate the clinical performance of PHAROS, a total of five images were obtained, including those from both patients and a normal control group. The images were then assessed by a nuclear medicine physician for clinical acceptability.

7.4 Sterilization and Shelf Life

Sterilization does not apply to this device as the device is non-sterile when used. Shelf life is not applicable to this device; however, instructions for cleaning and disinfection are listed in the operator manual.

7.5 Biocompatibility

The patient-contacting components are evaluated according to ISO 10993-1.

7.6 Software Verification and Validation Testing

Software Verification and Validation was completed according to IEC 62304.

The Risk Management report was completed according to ISO 14971.

8 Substantial Equivalence Summary

The similarities and differences between the devices are summarized below:

- The subject and predicate devices are PET nuclear medical scanning systems which employ similar design, construction, materials, energy source, operating principles, and technology.
- Slight differences in performance originate from design decisions including detector configuration.
- The subject device includes a patient chair. The basic safety of the patient chair has been verified.
- The subject and predicate have some of the same performance tests. The subject device passed all performance tests listed.

As shown in the comparison table above:

- Both devices have the same classification and product code.
- Both devices have similar indications for use and similar intended use.
- Both devices have similar technological characteristics.
- Both devices have similar performance.

The comparison analysis demonstrates the subject device is at least as safe and effective as the legally marketed predicate. Only minor differences were noted of the subject and predicate devices due to the shape, size and design; none raise new issues of safety or effectiveness.

Performance test data support the safety of the device and the hardware and software verification and validation demonstrate that the PHAROS should perform as intended in the specified use conditions. The sample images from five clinical cases supported the clinical effectiveness of the PHAROS. Based upon performance data, PHAROS is substantially equivalent to the predicate device.

9 Conclusion

The performance data provided demonstrate that PHAROS performs comparably to the predicate device and has a safety and effectiveness profile that is similar to the predicate device. Brightonix believes **PHAROS** is substantially equivalent to the legally marketed **BBX-PET Scanner**.