September 21, 2023

General Equipment for Medical Imaging, S.A.
% Dave Yungvirt
Chief Executive Officer
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K232569
Trade/Device Name: CareMiBrain
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS
Dated: August 21, 2023
Received: August 24, 2023

Dear Dave 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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

k232569

Device Name
CAREMIBRAIN

Indications for Use *(Describe)*

CareMiBrain is dedicated brain PET scanner, and intended to obtain Positron Emission Tomography (PET) images of human brain to detect abnormal pattern of distribution of radioactivity after injection of a positron emitting radiopharmaceutical. This device is to be used by trained healthcare professionals. 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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510(K) SUMMARY K232569

[As required by 21 CFR 807.92]

This 510(k) summary of safety and effectiveness information is prepared in accordance with 21 CFR 807.92

I. SUBMITTER´S INFORMATION

Submitter	General Equipment for Medical Imaging, S. A. (Oncovision Gem-Imaging S.A.) Calle de Jeroni de Montsoriu, 92 – BJ IZ 46022 Valencia +34 96 372 24 72 info@oncovision.com
510(K) Contact person	María Climent Vicedo Quality and Regulatory Affairs Manager General Equipment for Medical Imaging, S.A. Phone: (+34) 653 76 32 68 Email: calidad@oncovision.com
Date	13 Sep 2023

II. DEVICE

Trade / Device Name	CareMiBrain
Common Name	Dedicated brain Positron Emission Tomography system
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 Trade/Device Name	BBX™-PET Scanner
510(k) Number	K210450
Common Name	PET Scanner
21 CFR Reference	892.1200
Regulation Name	Emission Computed Tomography System
Classification	Class II
Panel	Radiology
Product Code	KPS
Applicant	Prescient Imaging LLC.

IV. APPLICABLE FDA GUIDANCES

This document has been prepared according to the required content described in the FDA Guidance *"The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k). Guidance for Industry and FDA"*, and *"Classification of Products as Drugs and Devices & Additional Product Classification Issues: Guidance for Industry and FDA Staff".*

V. DEVICE DESCRIPTION

CareMiBrain is a small aperture Positron Emission Tomography (PET) scanner to image the distribution of injected positron emitting radiopharmaceuticals in the head of live humans in seating/reclined position. CareMiBrain is a PET (Positron Emission Tomography) dedicated to brain imaging. All elements of the system are integrated into a compact volume, containing the detection system, acquisition and control electronics and software. All elements of the system are integrated into a compact volume, containing the detection system, acquisition and control electronics and software. The scanner consists of 48 monolithic Lutetium Yttrium OrthoSilicate (LYSO) crystals arranged in 3 rings of 16 modules each. Physical ring diameter is 260mm, with an effective 220 mm transaxial and 152 mm axial FOV. Crystal dimensions are 50x50x15mm (width x height x thickness). Crystals are coupled to a photosensor array of 12x12 silicon photo-multiplier (SiPM), 3x3 mm each. The detectors of the equipment are integrated in a circular housing with the appropriate dimensions so that the patient can insert the head. The software that integrates the equipment allows the acquisition, reconstruction and export of tomographic images of the brain, as well as to make a diagnosis of the state of the detectors.

The use of the device is limited only to patients whose height is higher than 140cm (55.2 inches).

VI. INDICATIONS FOR USE

CareMiBrain is dedicated brain PET scanner, and intended to obtain Positron Emission Tomography (PET) images of human brain to detect abnormal pattern of distribution of radioactivity after injection of a positron emitting radiopharmaceutical. This device is to be used by trained healthcare professionals. This information can assist in research, diagnosis, therapeutic planning and therapeutic outcome assessment.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

CareMiBrain and the predicate device are both Positron Emission Tomography systems used to image and measure the distribution of injected positron emitting radiopharmaceuticals in human beings. Main technological elements of CareMiBrain and predicate device are the same:

- PET detectors are arranged in a cylindrical shape.
- Detectors are composed of scintillator crystals and Silicon photomultipliers, that detect gamma rays emitted by radioactivity located inside the cylinder.
- Single and coincidence events are captured on detector electronics and acquired and processed by software, that generates image using iterative reconstruction methods.
- Attenuation correction method is in both cases Calculated Attenuation Correction.

Main differences between predicate device and CareMiBrain are:

- Patient is in seated/reclined position in CareMiBrain, while in predicate device is lying on a bed.
- Cylinder diameter is 26 cm in CareMiBrain, while in predicate device is 29cm.
- Crystals are monolithic Lutetium Yttrium OrthoSilicate (LYSO) in CareMiBrain, while in predicate pixelated lutetium fine-silicate (LFS) crystals are used.

VIII. COMPARISON TABLE

Attributes	**Predicate device** **BBX™-PET Scanner**	**Subject device** **CareMiBrain**	**Justification of equivalence**
Device			
Intended use	Dedicated Positron Emission Tomography	Dedicated Positron Emission Tomography	Same as predicate
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.	CareMiBrain is dedicated brain PET scanner, and intended to obtain Positron Emission Tomography (PET) images of human brain to detect abnormal pattern of distribution of radioactivity after injection of a positron emitting radiopharmaceutical. This device is to be used by trained healthcare professionals. This information can assist in research, diagnosis, therapeutic planning and therapeutic outcome assessment.	Same as predicate
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	CareMiBrain is a small aperture Positron Emission Tomography (PET) scanner to image the distribution of injected positron emitting radiopharmaceuticals in the head of live humans, as defined in 21 CFR 892.1200.	Same as predicate

	internal distribution of radioactivity in the head.	CareMiBrain generates tomographic images that represent the internal distribution of radioactivity in the patient's head and brain.	
Scintillator configuration / Scanner	Double-layer staggered Lutetium Fine Silicate pixelated crystals (13 × 13 and 14 × 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.	Monolithic Lutetium-based scintillator (LYSO) coupled to solid state silicon photomultiplier. Crystals are 50x50x15mm. 3 rings of 16 detectors positioned in circular shao. Bore diameter (opening detector) is 260mm and useful FOV is 220mm transaxial and 150mm axial.	Both use scintillator crystals coupled to solid state silicon photomultipliers in circular shape. Bore diameter is similar. Axial FOV is bigger for CareMiBrain. The most important innovation in the design of CareMiBrain PET scanner is the use of continuous crystals in contrast to standard pixelated crystals. CareMiBrain uses continuous crystals, which make it possible to measure multiple layers of depth of interaction (DOI) of the gamma rays in the crystals. This allows the system to minimize the parallax error which degrades the final spatial resolution. These differences do not affect the indications, only the performance
Target population	Adults, young adults	Adults and adolescent > 140cm height	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 allow imaging the breast, hand, or leg in a seated position.	PET detection system is fixed and includes a chair. Gantry can move up, down, horizontally and with tilt adjust to properly fit the height of the patients for imaging the brain while the patient is seated.	Only brain imaging in seating position is possible. This position is the same in predicate. Main difference is that the chair is integrated in the system, as explained in the discussion section. Imaging in lying position is not possible.
Design	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.	CareMiBrain is comprised of two parts; the PET scanner, that includes the patient's chair for acquisition in seated position and contains the electronics and detectors; and the control station, including the PC and the software for controlling the data acquisition and performing the reconstruction. Scanner and control station are connected through a dedicated network. Control station is connected to hospital's network with DICOM Worklist support and PACS connectivity.	Same as predicate, except that the connection is standard ethernet cable instead of a fiber optics cable and USB

Performance Data[1] (Specifications	Spatial Resolution: 2.2 mm FWHM Spatial resolution in FWHM at the center: 2.2mm Spatial resolution in FWHM at 10 cm: Not published Energy resolution: Not published Transverse resolution: 2.2mm Axial resolution: 2.2mm Spatial linearity: Not published Flood field uniformity: Not published System sensitivity: 1.1% Coincidence timing window: Not published Coincidence dead time: Not published	Spatial Resolution: 1.9 mm FWHM Spatial resolution in FWHM at the center: 1.55mm Spatial resolution in FWHM at 10cm: 1.66mm Energy resolution: < 20% Transverse resolution: 1.55mm Axial resolution; 1.45mm Spatial linearity: ±0,12mm Flood field uniformity: < 10% System sensitivity: >7% with 358-664 Kev window, >9% with 255-767 KeV window. Coincidence timing window: 5ns Coincidence dead time: 700ns	Performance is same or better than published predicate data. Based on the available, published performance of the predicate, the non-published predicate performance values cannot be better than CareMiBrain measured values, as they are highly related. A change in performance does not affect indications, as it is in all cases improving the images.

[1] Performance data for CareMiBrain published in Scientific Reports, (2019) 9:15484 | https://doi.org/10.1038/s41598-019-51898-z

	Scatter fraction: Not published Scatter correction method: Not published Slice thickness: Depends on reconstruction (2mm/4mm) Count rate sensitivity: 10 cps/kBq Isolation of the detector from background: Not applicable for PET Intrinsic spatial resolution: Not applicable for PET Attenuation: Calculated method Depth of Interaction: Double-layer Computer: GPU	Scatter fraction: 48% Scatter correction method: dual energy window Slice thickness: Depends on reconstruction (0.5/1/2mm) Count rate sensitivity: 13.82 cps/kBq with 255-767 KeV window, 11.05 cps/kBq with 358-664 Kev window. Isolation of the detector from background: Not applicable for PET Intrinsic spatial resolution: Not applicable for PET Attenuation: Calculated method Depth of interaction: < 4mm Computer: GPU	
Materials and biocompatibility	Standard electronic 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 electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic	Complies with standard ANSI/AAMI IEC 60601-1-2:2014. Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic	Same as predicate

	disturbances – Requirements and tests for EMC.	compatibility - Requirements and tests.	
Sterility	The product is not sterile and has not to be sterilized by the user. Cleaning standard procedure of medical devices.	The product is not sterile and has not to be sterilized by the user. Cleaning standard procedure of medical devices.	Same as predicate
Mechanical and electrical safety	Complies with standard 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	Complies with standard ANSI/AAMI ES 60601-1:2005 (Third Edition)/ (R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012. Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.	Same as predicate
Clinical efectiveness[2]	3 clinical images are provided from Prescient BBX-PET to demonstrate the image capability and the fulfillment with its predetermined specification.	More than 40 clinical images are provided from CareMiBrain to demonstrate the image capability and the fulfillment with its predetermined specification.	Same or better as predicate

IX. PERFORMANCE DATA

CareMiBrain performance has been independently tested, and the following data is provided in support of substantial equivalence determination. See in section 18 the Summary testing for each non-clinical test performed following the guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions".

[2] CareMiBrain clinical evaluation published in Rev Esp Med Nucl Imagen Mol., 2021. https://doi.org/10.1016/j.remn.2021.04.002

i. Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the CareMiBrain device and certified by independent certification company DEKRA and SGS. The system complies with the following standards:

- ANSI / AAMI ES 60601-1:2005 / (R) 2012 and A1:2012, C1:2009/ (R) 2012 and A2:2010/(R) 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 compatibility - Requirements and tests.

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)."

According to the FDA regulations, the CareMiBrain Level of Concern is "Moderate". A software malfunction cannot directly cause any harm to the patient but might lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that might lead to minor injury. But as the scope of the CareMiBrain Suite is to provide additional information to other techniques which are usually performed (pathologic analysis, etc.), the physician criteria would always prevail over it.

On the other hand, the software validation process has been designed following the ISO/IEC 62304 guidelines. According to ISO/IEC 62304, it must comply with level B in the security level, which equals to "Moderate Level of Concern" in FDA regulation.

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 NuclearTomography Systems" Section IX.C.2. (CDRH, 1998).

Performance CareMiBrain PET Scanner has been tested by an independent institute (Institute for Instrumentation of Molecular Imaging, i3m) according to NEMA NU 2-2012 (for whole-body PETs) and the results published in Scientific Reports Journal (DOI 10.1038/s41598-019-51898-z). The measurements performed include:

- Spatial Resolution
- Scatter Fraction and count rate (NECR)

- Sensitivity
- Image Quality, accuracy of attenuation correction and scatter correction
- Accuracy: corrections for count losses and randoms

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

For a better understanding of the performed tests, these have been following the NEMA NU 4-2008, the standard on performance measurement of small animal Positron Emission Tomographs, and NEMA NU 2-2018, used for performance measurements of human Positron Emission Tomographs.

This is because in some test the length of the ring prevented the NEMA NU 2-2018 from being followed. However, the NEMA NU 4-2008 tests are more restrictive.

Therefore, to establish an acceptance tolerance we have relied on other PETs, because when these tests were performed there was no dedicated brain PET available, as we can see in *Moliner, L., Rodríguez-Alvarez, M.J., Catret, J.V. et al. NEMA Performance Evaluation of CareMiBrain dedicated brain PET and Comparison with the whole-body and dedicated brain PET systems. Sci Rep 9, 15484 (2019).* https://doi.org/10.1038/s41598-019-51898-z

We provide a table with a summary of the bench test have been performed.

Performance Criteria	Results	CareMiBrain – PET scanner Acceptance criteria
Spatial Resolution (NEMA NU 4-2008)		
Transverse Resolution FWHM @5mm	1,55 mm	2 mm
Transverse Resolution FWHM @10mm	1,45 mm	2 mm
Transverse Resolution FWHM @15mm	1,52 mm	2 mm
Transverse Resolution FWHM @25mm	1,59 mm	2 mm
Axial Resolution FWHM @5mm	1,45 mm	2 mm
Axial Resolution FWHM @10mm	1,40 mm	2 mm
Axial Resolution FWHM @15mm	1,58 mm	2 mm
Axial Resolution FWHM @25mm	1,41 mm	2 mm
Radial Resolution FWHM @5mm	1,51 mm	2 mm
Radial Resolution FWHM @10mm	1,58 mm	2 mm
Radial Resolution FWHM @15mm	1,64 mm	2 mm
Radial Resolution FWHM @25mm	1,52 mm	2 mm
Extra spatial resolution values (NEMA NU 4-2008).		
Transverse Resolution FWHM @0 mm	1,53 mm	2 mm
Transverse Resolution FWHM @50 mm	1,51 mm	2 mm
Transverse Resolution FWHM @75 mm	1,76 mm	2 mm
Transverse Resolution FWHM @100mm	1,66 mm	2 mm
Axial Resolution FWHM @0 mm	1,36 mm	2 mm
Axial Resolution FWHM @50 mm	1,44 mm	2 mm
Axial Resolution FWHM @75 mm	1,44 mm	2 mm

Axial Resolution FWHM @100mm	1,44 mm	2 mm
Radial Resolution FWHM @0 mm	1,57 mm	2 mm
Radial Resolution FWHM @50 mm	1,67 mm	2 mm
Radial Resolution FWHM @75 mm	1,64 mm	2 mm
Radial Resolution FWHM @100mm	1,64 mm	2 mm
Spatial resolution (NEMA NU 2-2012).		
Transverse Resolution FWHM @10mm	1,68 mm	2 mm
Transverse Resolution FWHM @100mm	1,86 mm	2 mm
Axial Resolution FWHM @10 mm	1,39 mm	2 mm
Axial Resolution FWHM @100 mm	1,40 mm	2 mm
Radial Resolution FWHM @10 mm	1,87 mm	2 mm
Radial Resolution FWHM @100 mm	1,86 mm	2 mm
Count rate evaluation and sensitivity (NEMA NU 2-2012).		
Sensitivity along transverse center	17,83 cps/kBq	15 cps/kBq
Sensitivity off center	13,82 cps/kBq	12cps/kBq
Count rate peak NECR	49 kcps	30 kcps
Count rate peak trues	193 kcps	160 kcps
Scatter fraction at peak NECR	7,4 MBq	9,25 MBq
Scatter fraction Mean	48 %	60 %
Image Quality - % contrast/ background variability (NEMA NU 4-2008).		
4,5 mm	0,73	0,65
6mm	0,78	0,65
9mm	1,14	0,65
12mm	1,01	0,65

iv. Performance Testing – Animal

Not applicable

v. Performance Testing - Clinical

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).

Clinical effectiveness has been tested by independent hospitals and the results published in Spanish Journal of Nuclear Medicine and Molecular imaging (DOI 10.1016/j.remn.2021.04.002)

Sample images from several clinical cases with different PET tracers using the CareMiBrain PET Scanner were provided.

X. CONCLUSION

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