July 15, 2024

Positrigo AG
% Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd
Warren, New Jersey 07059

Re: K241751
Trade/Device Name: NeuroLF (Basic); NeuroLF (Pro); NeuroLF (Advanced); NeuroLF Seat
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS
Dated: June 20, 2024
Received: June 21, 2024

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 (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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241751

Device Name
NeuroLF (Basic);NeuroLF (Pro); NeuroLF (Advanced); NeuroLF Seat

Indications for Use *(Describe)*
NeuroLF is a positron emission tomography system that is used to detect and display the distribution of positron-emitting radionuclides within parts of the human body to assist in diagnosis, therapeutic planning, and therapeutic outcome assessment. The NeuroLF seat is intended to properly position the patient for PET imaging of the neck or head with the NeuroLF.

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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1. Contact Details:

Company Name:	Positrigo AG
Address:	Technoparkstrasse 1, 8005 Zürich, Switzerland
Contact Name:	Mr. Jannis Fischer
Phone:	0041 44 515 53 30
Email:	jannis.fischer@positrigo.com

2. Device Name:

Device trade name:	NeuroLF Basic NeuroLF Pro NeuroLF Advanced NeuroLF Seat
Common name:	PET Scanner
Classification name:	Emission computed tomography system
Regulation number:	892.1200
Product code:	KPS

3. Legally Marketed Predicate Device:

Predicate device application number:	K210450
Predicate trade name:	BBX-PET Scanner
Predicate product code:	KPS

4. Device description summary:

The NeuroLF is a small aperture Positron Emission Tomography (PET) scanner that produces images of the distribution of positron-emitting isotopes from parts of a subject that are put into the aperture for medical diagnostic purposes. The NeuroLF System comprises the Scanning Unit and the Patient Positioning System (NeuroLF Seat). The circular opening in the scanner head has an effective inner diameter of 260mm and is designed such that the entire brain fits within the scanner's field of view (FoV). With a length of an axial FoV of 163mm, the NeuroLF is designed to capture a single image. The NeuroLF scanner head consists of an octagonal detector, which is composed of 8 detector modules. Each module contains a total of 384 Lutetium Yttrium Orthosilicate (LYSO) Crystals. The software of the NeuroLF System integrates the equipment, allows acquisition, reconstruction and export of tomographic images.

It also allows the user to detect the current state of the running system. The device shall only be used with patients whose weight is lower than 200kg (440lb).

There are three different versions of the NeuroLF; 10 mm (NeuroLF Basic), 15 mm (NeuroLF Pro) and 20 mm (NeuroLF Advanced). The number corresponds to the length of the LYSO crystals in the detector modules. The absorption probability of gamma radiation is proportional to the volume of scintillating material in the scanner and therefore the highest absorption probability is to be expected from the 20 mm detectors. The longer the LYSO crystals the higher the sensitivity of the device, therefore in clinical use the acquisition time or the activity in the field of view could be reduced.

5. Intended Use/Specification for Use:

NeuroLF is a positron emission tomography system that is used to detect and display the distribution of positron-emitting radionuclides within parts of the human body to assist in diagnosis, therapeutic planning, and therapeutic outcome assessment. The NeuroLF seat is intended to properly position the patient for PET imaging of the neck or head with the NeuroLF.

6. Indications for Use Comparison:

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.

7. Technological Comparison:

NeuroLF 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 NeuroLF 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 images using iterative reconstruction methods.
- Attenuation correction method is in both cases Calculated Attenuation Correction.
- Main differences between predicate device and NeuroLF are:
- Patient is in a seated/reclined position in NeuroLF, while the predicate device is lying on a bed.
- Cylinder diameter is 26 cm in NeuroLF, while in predicate device is 29cm.

- Crystals are Lutetium Yttrium OrthoSilicate (LYSO) in NeuroLF, while in predicate lutetium fine-silicate (LFS) crystals are used.

7.1. Comparison Table:

Attributes	**Predicate device BBX-PET Scanner**	**Subject device NeuroLF**	**Justification of equivalence**
Device			n/a
Intended Use	Dedicated Positron Emission Tomography	Dedicated Positron Emission Tomography	Same as predicate
Indication for use	BBX-PET is 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 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.	NeuroLF is a positron emission tomography system that is used to detect and display the distribution of positron-emitting radionuclides within parts of the human body to assist in 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	NeuroLF is a small aperture Positron Emission Tomography (PET) scanner to image the distribution of	Same as predicate

	radiopharmaceuticals into live humans or animals. The BBX-PET Scanner produces images that represent the internal distribution of radioactivity in the head.	injected positron emitting radiopharmaceuticals in the head of live humans, as defined in 21 CFR 892.1200. NeuroLF generates tomographic images that represent the internal distribution of radioactivity in the patient's brain.	
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 in light-sharing architecture with silicon photomultipliers. A single crystal array is composed of 4x4 scintillators. The pitch of the crystals is 3.19 mm. Overall, 12288 pixels disposed in octagonal shape forms the detection ring. The transaxial FoV is 268 mm, the axial FoV is 164 mm.	Detectors design and fields of view are similar. NeuroLF axial FoV is longer. While the pitch for NeuroLF is larger, the use of a single layer of scintillators facilitates the correct assignment of the gamma absorption location. 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	Detects distribution of radioactivity after injection	Detects distribution of radioactivity after injection of	Same as predicate

delivered	of a positron emitting radiopharmaceutical. No energy delivered.	a positron emitting radiopharmaceutical. No energy delivered.	
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.	The PET detection system is fixed and includes a chair. Gantry can be manually moved up, down, horizontally and with tilt adjusted to properly fit the height of the patient for imaging the brain while the patient is seated.	Only brain imaging in a seated position is possible. This position is the same as in predicate. Main difference is that the chair is part of the system, as explained in the discussion section. Imaging in a 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 the computer contains workstation. These two parts are connected to each other using optical fiber and an USB cable.	NeuroLF has three separable parts. The NeuroLF Seat is used to place the subject's head precisely in the Detector Ring. The Scanning Unit contains the Detector Ring that performs the data acquisition with custom electronics, a Scanning Computer System located in the gantry and the Reconstruction Computer System performing tomographic image reconstruction. The NeuroLF system comes with two User Interfaces.The first is located on the gantry of the Scanning Unit and is used for monitoring, starting, and interrupting scans directly next to the patient. The	Same as predicate, that the except connection is standard ethernet cable instead of a fiber optics cable and USB

		second User interface is an application on a separate Console Computer System. Scanning Unit and Console Computer System are connected by ethernet cable with and through the hospital network. The system has DICOM Worklist support and PACS connectivity.	
Performance Data Specifications	Spatial resolution in FWHM at the center: 2.2mm Spatial resolution in FWHM at 10 cm: Not published 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	Spatial resolution in FWHM at 1 cm: 2.7 mm (NeuroLF Basic) 3.1 mm (NeuroLF Advanced) Spatial resolution in FWHM at 10 cm: 3.5 mm (NeuroLF Basic) 3.7 mm (NeuroLF Advanced) Energy resolution: 17-25% FHWM System sensitivity: 3.1% (NeuroLF Basic) (NEMA-NU4-2008) Coincidence timing window: 3ns-5ns Scatter fraction: 38% (NeuroLF Basic) (NEMA-NU2-2018) Scatter correction method: SSS - single scatter simulation Slice thickness: 1.66 mm	

	(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 Computer: GPU	Count rate sensitivity: 4.8 cps/kBq (center), 6.8 cps/kBq (100mm) (NeuroLF Basic) (NEMA-NU2-2018) Isolation of the detector from background: Not applicable for PET Intrinsic spatial resolution: Not applicable for PET Attenuation: Calculated method Computer: CPU	
Materials and bio-compatibility	Standard electronics and medical grade materials	Standard electronics 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 Medical equipment electrical Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic compatibility-requirements and tests.	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	Complies with standard IEC (Third 60601-:2005 Edition)	Complies with standard IEC (Third 60601-1:2005 Edition)	Same as predicate

safety	+ COOR.1:2006 + CORR.2:2007 + A1:2012 Medical equipment electrical Part 1: General requirements for basic safety and essential performance for electrical safety	+ COOR.1:2006 + CORR.2:2007 + A1:2012 + A2:2020 Medical equipment electrical Part 1: General requirements for basic safety and essential performance for electrical safety	
Clinical effectiveness	3 clinical images are provided from Prescient BBX-PET to demonstrate the image capability and the fulfillment with its predetermined specification.	4 clinical images are provided by Positrigo AG from NeuroLF to demonstrate the image capability and the fulfillment with its predetermined specification.	Same or better as predicate

8. Performance Data:

8.1. Electrical safety and electromagnetic compatibility (EMC):

Electrical safety and EMC testing were conducted on the NeuroLF System and certified by the independent certification company TÜV SÜD Product Service GmbH. The system complies with:

- IEC 60601-1:2005 / A1:2012 / A2:2020. Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- 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.

8.2. Software Verification and Validation testing:

Software verification and validation is conducted and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of premarket submission for Device Software Functions (CDRH, 2023).
According to the referred FDA guidance, the software documentation level is classified as basic. A failure or latent flaw of the device software function(s) would not present a hazardous situation with a probable risk of death or serious injury to either a patient, user of the device, or others in the environment of use, prior to the implementation of risk control measures.

8.3. 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).
The performance of the NeuroLF System has been tested by Positrigo AG according to NEMA NU-2:2018 - Performance Measurements of Positron Emission Tomography. The testing performed include:

- Spatial resolution
- Scatter Fraction and count rate (NECR)
- Sensitivity
- Accuracy: Corrections for count losses and randoms
- Image quality, accuracy of corrections

Test results indicate that the NeuroLF System complies with its predetermined specifications and the applicable standards.

8.4. 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 notification for Emission computed Tomography Devices and accessories (SPECT and PET) and nuclear Tomography Systems" Section IX.F: (CDRH, 1998).

Sample images from four clinical cases using the NeuroLF System were provided.

9. Conclusion:

The data support the safety of the device and the hardware and software verification and validation demonstrate that the NeuroLF System should perform as intended in the specified use conditions. The publication including the sample images from four clinical cases supported the clinical effectiveness of the NeuroLF system. Based upon performance data the NeuroLF System is substantially equivalent to the predicate device.