August 10, 2023

XEOS Medical
% Bjorn Delbeecke
Head of QARA and Legal
Ottergemsesteenweg-Zuid 808
Bus 358
Gent, Oost-Vlaanderen 9000
BELGIUM

Re: K231420
Trade/Device Name: AURA 10 PET-CT
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: QXL, MWP
Dated: May 5, 2023
Received: May 16, 2023

Dear Bjorn Delbeecke:

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)*

K231420

Device Name

AURA 10 PET/CT

Indications for Use *(Describe)*

The AURA 10 PET/CT system is a cabinet diagnostic imaging device that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT) systems. The AURA 10 PET/CT system images harvested specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the surgical procedure. Images can be obtained as CT only, PET only, or a combination of both by surgeon's discretion.

The AURA 10 cabinet PET/CT system provides an image of extent and degree of intensity radiopharmaceutical uptake in the specimen by PET and the anatomical information by CT, which will help the surgeon with further patient management.

The AURA 10 PET/CT system is not validated for margin detection.

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

K231420

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

5.1. General information

Date Prepared: 5 May 2023

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Device:

Trade Name:	AURA 10 PET/CT
Common Name:	Cabinet, Emission Tomography System Cabinet, CT system
Classification Name (Regulation):	Cabinet, Emission Tomography System Cabinet, CT system
Classification Panel:	Radiology
Device Class	Class II
Product Code	QXL
Secondary product code	MWP

Predicate Device:

Trade Name:	Vereos Pet/Ct
Company:	Philips Medical Systems Nederland B.V.
510(k) Clearance:	K210880
Classification Name (Regulation):	Emission computed tomography system (21 CFR 892.1200) Computed tomography x-ray system (21 CFR 892.1750)
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	KPS
Secondary Product Code:	JAK

Reference Device:

Trade Name:	Faxitron Visionct
Company:	Faxitron Bioptics Llc
510(k) Clearance:	K173309
Classification Name (Regulation):	Stationary x-ray system (21 CFR 892.1680)
Classification Panel:	Radiology
Device Class:	Class II
Product Code:	MWP

Device description: The AURA 10 PET/CT is a mobile, vertical-bore PET/CT system with a Field of View (FOV) suitable for small pathology specimens. It is intended to be used in both the operating room (OR) as well as the pathology department to image pathology specimens from various anatomical regions in order to provide rapid pathology imaging. The AURA 10 PET/CT is intended to image pathology specimens for a wide range of patient types, sizes, and extent of diseases. It is designed as a mobile cart so that it is easily portable by one person and can be moved to different surgical suites or between departments as needed.

Intended Use / Indications for Use The AURA 10 PET/CT system is a cabinet diagnostic imaging device that combines Positron Emission Tomography (PET) and X-ray Computed Tomography (CT)

systems. The AURA 10 PET/CT system images harvested specimens from various anatomical regions in order to provide rapid verification that the correct tissue has been excised during the surgical procedure. Images can be obtained as CT only, PET only, or a combination of both by surgeon's discretion.

The AURA 10 cabinet PET/CT system provides an image of extent and degree of intensity radiopharmaceutical uptake in the specimen by PET and the anatomical information by CT, which will help the surgeon with further patient management.

The AURA 10 PET/CT system is not validated for margin detection.

Technological characteristics

The following table provides a detailed overview of the technological similarities and differences between the subject AURA 10 PET/CT, the predicate Vereos PET/CT and the reference device Faxitron Vision CT.

Features	Subject device AURA 10 PET/CT	Predicate device Vereos PET/CT (K210880)	Reference device Faxitron Vision CT (K173309)
GENERAL			
Size(s)	162 x 52 x 65 cm^3	485 x 220 x 207 cm^3 (L x W x H)	180 x 70 x 65 cm^3
Mass	150 kg	4220 kg	140 kg
Battery or Mains powered	Mains	Mains	Mains
Power requirements	Single-phase 110 – 250 VAC 50/60 Hz 1.2 kW	3-phase 200/208/240/380/400/415/4 80/500 VAC 50/60 Hz 150,000 VA	Single-phase 100 – 250 VAC 50/60 Hz 200 VA
Mobility	Mobile	Stationary	Mobile
PET SUBSYSTEM			
Scintillator Crystal Material	LYSO	LSO/LYSO	N/A
Photomultiplier technology	Silicon Photomultipliers	Silicon Photomultipliers	N/A
FOV, Transaxial	100 mm	576 mm	N/A
FOV, Axial	60 mm	164 mm	N/A
Energy Window	358 keV – 664 keV	450 – 613 keV	N/A
Spatial Resolution	< 1.0 mm	> 4.2 mm	N/A
Peak NEC Rate	38,395 kpcs at 26.6 kBq/mL	687 kcps @ 50 kBq/mL 222 kcps @ 5.3 kBq/mL	N/A
ToF Resolution	N/A	310 ps	N/A
Scatter fraction	16%	34%	N/A
Max Count rate Error	N/A	6.8%	N/A
Energy resolution	18%	11%	N/A
Sensitivity	60 cps/kBq	5.2 cps/kBq	N/A
CT SUBSYSTEM			
X-ray tube anode material	Tungsten	Tungsten	Tungsten
X-ray tube kV settings	50 kV	80, 100, 120, 140 kV	15 – 50 kv
X-ray tube current	1.0 mA max (0.6 mA actual)	20 – 665 mA	1.0 mA max
X-ray tube power	50 W max	80,000 W max	11.5 W max
Focal spot size	0.050 mm typical	0.5 x 1.0 mm^2 or 1.0 x 1.0 mm^2	< 0.015 mm
Anode angle	20 degrees	7 degrees	45 degrees
Focus-isocenter distance	260 mm	570 mm	230 mm
Focus-detector distance	350 mm	1040 mm	370 mm
Magnification	1.35X	1.82X	1.61X
Transaxial Modulation Transfer Function (MTF)	5 lp/mm (at cutoff) 4 lp/mm (at 20% MTF)	1.3 – 2.4 lp/mm (at cutoff)	Unpublished
Axial MTF	5 lp/mm (at cutoff) 4 lp/mm (at 20% MTF)	1.3 – 2.4 lp/mm (at cutoff) with appropriately thin slice sensitivity profile selection	Unpublished
Image matrix	1024 x 1024	Up to 1024 x 1024	1024 x 1024
Image matrix pixel size	0.1 mm x 0.1 mm	1 – 2 mm	0.1 mm x 0.1 mm

Slice thickness	0.1 mm	0.5 – 12.5 mm (axial mode)	0.1 mm
Number of slices	620	64, 128	Up to 1024
Metal artifact reduction	Yes	Available as option	Yes
HOST AND NETWORKING			
Network connection	Yes	Yes	Yes
PRESCRIPTION / OVER THE COUNTER			
Prescription / Over the counter	Prescription	Prescription	Prescription

Summary of non-clinical performance data

Electrical Safety and Electromagnetic Compatibility (EMC)

The AURA 10 PET/CT was tested in accordance with IEC 61010-1 (2010 + A1 2016) *Standard for Safety for Electrical Equipment for Measurement, Control and Laboratory Use – Part 1: General requirements*, including US deviations. The device passed all tests.

The AURA 10 PET/CT was tested in accordance with IEC 61010-2-091:2012 *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-091: Particular requirements for cabinet X-ray systems.* The device passed all tests. The device was also designed and developed in accordance to 21 CFR 1020.40 (Cabinet x-ray systems) and as recommended by FDA's Guidance for Industry and FDA Staff, "Compliance guide for cabinet X-ray systems."

The AURA 10 PET/CT was tested in accordance with IEC 61010-2-101:2018 2012 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.

The AURA 10 PET/CT was tested in accordance with IEC 61326-2-6 *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment.* The device passed all tests. The testing was conducted and documentation provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for electromagnetic compatibility (EMC) of medical devices."

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." The software for this device was considered as a moderate level of concern.

The AURA 10 PET/CT was tested in accordance with IEC 62304:2006 + A1:2015: Medical device software – Software life-cycle processes (FDA Recognition Number: 13-79).

Bench Testing

The following bench testing was performed to demonstrate substantial equivalence:

- Analytical performance testing. The AURA 10 PET/CT was tested in accordance with NEMA NU 4-2008 *Performance measurements of small animal positron emission tomographs (PETs).*
- Usability testing. The AURA 10 PET/CT was tested in accordance with IEC 62366-1:2015: *Medical devices – Part 1: Application of usability engineering to medical devices* (FDA Recognition Number: 5-114). Usability testing was conducted and documentation provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance on Applying Human Factors and Usability Engineering to Medical Devices".

Information pursuant to the following FDA Guidance Documents was also included:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

- Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions
- Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions
- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices
- Guidance for Radio Frequency Wireless Technology in Medical Devices
- Guidance for Off-The-Shelf Software Use in Medical Devices
- Guidance on General Principles of Software Validation
- Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems.

Summary of clinical performance data

Not applicable. Clinical studies are not necessary to establish the substantial equivalence of this device.

Final Conclusion

This summary includes information on the technological characteristics, performance data as well as verification and validation activities demonstrating that the AURA 10 PET/CT is as safe and effective as the predicate and does not raise different questions of safety and effectiveness, and therefore is substantially equivalent to the predicate device.