July 16, 2026

Cubresa, Inc.
℅ Sanjay Shah
Regulatory Affairs Consultant
Device Pathways, LLC
5054 Merrimac Ln N
Plymouth, Minnesota 55446

Re: K253963
Trade/Device Name: Cubresa BrainPET™
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission Computed Tomography System
Regulatory Class: Class II
Product Code: OUO, LNH, MOS, KPS
Dated: June 21, 2026
Received: June 22, 2026

Dear Sanjay Shah:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Digitally signed by Michael D. O'hara -S
Date: 2026.07.17 13:17:11 -04'00'

For

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253963

Please provide the device trade name(s).

Cubresa BrainPET™

Please provide your Indications for Use below.

The Cubresa BrainPET is a Positron Emission Tomography (PET) scanner, containing MR transmit and Receive head coils, and is intended for use with the Siemens Biograph mMR with syngo software to provide high resolution physiologic and anatomic information via PET and MR modalities acquired simultaneously and isocentrically. The Cubresa BrainPET maintains independent functionality of the MR and PET devices, allowing for single-modality MR or simultaneous PET/MR imaging.

The Cubresa BrainPET is intended to be utilized by appropriately trained health care professionals to aid in the detection, localization, and diagnosis of diseases and disorders of the brain.

The Cubresa BrainPET MR Coil is intended to produce transverse, sagittal, coronal, and oblique cross-sectional MR images, spectroscopic images and/or spectra, and displays the internal structure and/or function of the human brain.

The Cubresa BrainPET images and measures the distribution of PET radiopharmaceuticals in human head to aid in the evaluation of various metabolic (molecular) and physiologic functions within the human brain for evaluation of diseases and disorders such as, but not limited to, neurological diseases and disorders.

The Cubresa BrainPET utilizes the MR for radiation-free attenuation correction maps for PET studies. The system provides inherent anatomical reference for the PET and MR images due to precisely aligned MR and PET image coordinate systems.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K253963

510(k) Summary

This 510(k) summary is submitted in accordance with the requirements of 21 CFR §807.92.

I. SUBMITTER

Establishment: Cubresa Inc.
136 Market Ave. Suite 800 Winnipeg MB R3B 0P4
Canada
Registration Number: N/A

Date Prepared: July 16, 2026

Applicant Contact Lisa Bako
VP Sales & Strategic Partnerships
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Correspondent Contact Device Pathways LLC
Mr. Sanjay Shah
Regulatory Affairs Consultant
Telephone: 612-812-6462
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II. DEVICE

Device Trade Name: Cubresa BrainPET™
Common Name: Emission computed tomography system
Classification Name: Tomographic Imager Combining Emission Computed Tomography with Nuclear Magnetic Resonance
Regulatory Class: II
Regulation Number: 21 CFR § 892.1200
21 CFR § 892.1000
Product Codes: Primary: OUO
Secondary: LNH, MOS, KPS

III. PREDICATE DEVICE

Device Name: Biograph mMR with syngo MR E11P system software
510(k) Number: K163234
Common Name: Emission computed tomography system
Classification Name: Tomographic Imager Combining Emission Computed Tomography with Nuclear Magnetic Resonance
Regulatory Class II
Regulation Number: 21 CFR § 892.1200
21 CFR § 892.1000

Product Code: Primary: OUO
Secondary: LNH, LNI, KPS

IV. DEVICE DESCRIPTION

The Cubresa BrainPET system is a removable positron emission tomography (PET) scanner with an integrated magnetic resonance imaging (MRI) coil. It is designed for insertion into a magnetic resonance imager (MRI) scanner, enabling hybrid PET/MR imaging of the brain, and is configured for use with the Siemens Biograph mMR with syngo software. The Cubresa BrainPET system maintains independent functionality of the MRI for single modality MR imaging or quickly enables simultaneous PET/MRI imaging of the brain.

The Cubresa BrainPET insert assembly is MR-conditional and has a cylindrical shape, with an axial length of 200 mm, ensuring ample coverage of the entire human head, and produces images of the distribution of PET radiopharmaceuticals within the brain of the subject being imaged. The PET camera has a dual layer offset scintillator design with Lutetium Yttrium Orthosilicate (LYSO), with 64 detector modules arranged in a cassette fashion across 4 identical PET rings. The custom-designed actively decoupled Transmit (Tx) and Receive (Rx) head coil slides into the inner diameter of the PET camera and is plugged directly into the MRI scanner to enable acquisition of MR images simultaneously with PET data. The Tx portion of the coil consists of 8 elements arranged in a circular birdcage orientation around the cylinder, while the 32 circular Rx elements are distributed over the entire helmet area to ensure adequate brain coverage. The insert is stored on an MR-conditional cart which facilitates movement of the insert around the MR suite as well as mounting and demounting of the insert on to the bed of the MRI scanner.

An electromagnetic (EM)-quiet cabinet containing a data acquisition chassis is located within the MR suite and connected to the insert via copper cabling. The cabinet is connected via fiber to a workstation in the MR equipment room and then routed to the control room. The workstation consists of a computer pre-loaded with Cubresa acquisition and reconstruction software which enables system calibration, attenuation map creation, data reconstruction, and export of reconstructed DICOM-tagged data to the user's picture archiving system and subsequent visualization on third party software.

V. INDICATIONS FOR USE

The Cubresa BrainPET is a Positron Emission Tomography (PET) scanner, containing MR transmit and Receive head coils, and is intended for use with the Siemens Biograph mMR with syngo software to provide high resolution physiologic and anatomic information via PET and MR modalities acquired simultaneously and isocentrically. The Cubresa BrainPET maintains independent functionality of the MR and PET devices, allowing for single-modality MR or simultaneous PET/MR imaging.

The Cubresa BrainPET system is intended to be utilized by appropriately trained health care professionals to aid in the detection, localization, and diagnosis of diseases and disorders of the brain.

The Cubresa BrainPET MR Coil is intended to produce transverse, sagittal, coronal, and oblique cross-sectional MR images, spectroscopic images and/or spectra, and displays the internal structure and/or function of the human brain.

The Cubresa BrainPET images and measures the distribution of PET radiopharmaceuticals in the human head to aid in the evaluation of various metabolic (molecular) and physiologic functions within the human brain for evaluation of diseases and disorders such as, but not limited to, neurological diseases and disorders.

The Cubresa BrainPET utilizes the MR System for attenuation correction maps for PET studies. The system provides inherent anatomical reference for the PET and MR images due to precisely aligned MR and PET image coordinate systems.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Cubresa BrainPET is shown to be substantially equivalent to the predicate device Siemens Biograph mMR with syngo software by comparing the indications for use, principles of operation, technological characteristics, and performance testing similarities and differences.

The technological characteristic similarities and differences between the proposed Cubresa BrainPET and the Siemens Biograph mMR with syngo software predicate device are listed in Table 1.

The components used in the Cubresa BrainPET, including the insert assembly, electromagnetic-quiet cabinet, MR-conditional lift and storage device and workstation are substantially equivalent to the predicate Siemens Biograph mMR. While there are differences in technological characteristics for the Cubresa BrainPET compared to the predicate device, the differences have been tested and the conclusions from the verification and validation data support that the technological characteristics of the Cubresa BrainPET have an equivalent safety and performance profile to that of the Biograph mMR with syngo software predicate device (K163234). Successful completion of the standard QA tests and expert review of sample clinical images demonstrate that the Cubresa BrainPET maintains clinically acceptable MR and PET imaging performance. Based on the substantial equivalence analysis, the proposed Cubresa BrainPET is substantially equivalent to the predicate device.

Table 1 – Substantial Equivalence

Characteristic	Predicate Device Siemens Biograph mMR with syngo MR E11P system software (K163234)	Proposed Device Cubresa BrainPET	Equivalence Comparison
Trade/Device Name	Biograph mMR with syngo MR E11P system software	Cubresa BrainPET™	N/A
Regulation Number:	21 CFR § 892.1200 21 CFR § 892.1000	21 CFR § 892.1200 21 CFR § 892.1000	Same
Device Class	Class II	Class II	Same
Product Code	Primary: OUO Secondary: LNH, LNI, KPS	Primary: OUO Secondary: LNH, MOS, KPS	Same
Classification	Tomographic Imager	Tomographic Imager	Same

Characteristic	Predicate Device Siemens Biograph mMR with syngo MR E11P system software (K163234)	Proposed Device Cubresa BrainPET	Equivalence Comparison
Name:	Combining Emission Computed Tomography with Nuclear Magnetic Resonance	Combining Emission Computed Tomography with Nuclear Magnetic Resonance	
Panel	Radiology	Radiology	Same
Intended Use/Indications for Use	The Siemens MR-PET system combines magnetic resonance diagnostic devices (MRDD) and Positron Emission Tomography (PET) scanners that provide registration and fusion of high resolution physiologic and anatomic information, acquired simultaneously and isocentrically. The combined system maintains independent functionality of the MR and PET devices, allowing for single modality MR and / or PET imaging. These systems are intended to be utilized by appropriately trained health care professionals to aid in the detection, localization, and diagnosis of diseases and disorders. The MR is intended to produce transverse, sagittal, coronal and oblique cross-sectional MR images, spectroscopic images and/or spectra, and displays the internal structure and/or function of the human body. Other physical parameters derived from the images and/or spectra may also be produced. Depending on the region of interest, approved contrast agents may be used, as described in their labeling. This	The Cubresa BrainPET is a Positron Emission Tomography (PET) scanner, containing MR transmit and Receive head coils, and is intended for use with the Siemens Biograph mMR with syngo software to provide high resolution physiologic and anatomic information via PET and MR modalities acquired simultaneously and isocentrically. The Cubresa BrainPET maintains independent functionality of the MR and PET devices, allowing for single-modality MR or simultaneous PET/MR imaging. The Cubresa BrainPET is intended to be utilized by appropriately trained health care professionals to aid in the detection, localization, and diagnosis of diseases and disorders of the brain. The Cubresa BrainPET MR Coil is intended to produce transverse, sagittal, coronal, and oblique cross-sectional MR images, spectroscopic images and/or spectra, and displays the internal structure and/or function of the human brain.	Same

Characteristic	Predicate Device Siemens Biograph mMR with syngo MR E11P system software (K163234)	Proposed Device Cubresa BrainPET	Equivalence Comparison
	system may also be used for imaging during interventional procedures when performed with MR compatible devices, such as MR safe biopsy needles. The PET images and measures the distribution of PET radiopharmaceuticals in humans to aid the physician in determining various metabolic (molecular) and physiologic functions within the human body for evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The combined system utilizes the MR for radiation-free attenuation correction maps for PET studies. The system provides inherent anatomical reference for the fused PET and MR images due to precisely aligned MR and PET image coordinate systems.	The Cubresa BrainPET images and measures the distribution of PET radiopharmaceuticals in human head to aid in the evaluation of various metabolic (molecular) and physiologic functions within the human brain for evaluation of diseases and disorders such as, but not limited to, neurological diseases and disorders. The Cubresa BrainPET utilizes the MR for radiation-free attenuation correction maps for PET studies. The system provides inherent anatomical reference for the PET and MR images due to precisely aligned MR and PET image coordinate systems.	
PET system technology			
Axial field of view	258 mm	200 mm	Equivalent
Transaxial field of view	594 mm	320 mm	Equivalent
Scintillators	Lutetium Orthosilicate (LSO)	Lutetium Yttrium Orthosilicate (LYSO)	Equivalent
Crystal cut	Crystal cut	Dual-layer offset design	Equivalent

Characteristic	Predicate Device Siemens Biograph mMR with syngo MR E11P system software (K163234)	Proposed Device Cubresa BrainPET	Equivalence Comparison
Photodetectors	Avalanche Photodiodes (APDs) (water-cooled)	Silicon Photomultipliers (SiPMs)	Equivalent
PET data acquisition electronics	Housed within the body of the predicate device's PET system	Electronics housed within an EM-quiet cabinet located in the MR suite	Equivalent
PET camera storage mechanism	Predicate device, which has an integrated PET camera, is permanently fixed in place within a dedicated MR suite and does not required storage	Insert portion of the proposed device stored on a rolling cart that permits movement of the device around the MR suite to facilitate loading/unloading onto the bed of the MRI (when in use) and storage at the back of the MR suite (when not in use).	Equivalent
MRI System Technology Characteristics			
Field strength	3T	3T	Same
Bore strength	60 cm	60 cm	Same
System length	199 cm	199 cm	Same
System weight (in operation)	6.3 tons	6.3 tons	Same
Gradient strength	MQ gradients (45 mT/m @ 200 T/m/s)	MQ gradients (45 mT/m @ 200 T/m/s)	Same
Coil	Siemens mMR Head/Neck Matrix coil	1H 1Tx32Rx Head Array	Different
MR atomic nuclei	1H	1H	Same
RF polarization	Linear	Quadrature	Equivalent
Field strength B0	3T	3T	Equivalent

Characteristic	Predicate Device Siemens Biograph mMR with syngo MR E11P system software (K163234)	Proposed Device Cubresa BrainPET	Equivalence Comparison
Operating frequency	123.2 MHz	123.2 MHz	Same
Signal to noise ratio (SNR)	Compliance with recognized standard test method	Compliance with NEMA MS1 test method	Equivalent
RF induced heating (SAR)	Compliance with IEC 60601-2-33	Compliance with IEC 60601-2-33	Equivalent
Software & Algorithms			

PET-related	• Operating system: Microsoft Windows
	• Listmode data acquisition in 3D mode (static, multibed)
	• PET Reconstruction:
	  ○ Analytical: filtered back-projection (FBP)
	  ○ Iterative: 3D ordinary Poisson ordered subset expectation maximization (OSEM)
	• Attenuation correction approaches:
	  ○ MRAC (4 DIXON sequences)
	  ○ MRextendedFOV (HUGE)
	  ○ UTE-based
	• Scatter correction: Relative and Absolute Scaling
	• Dynamic imaging
	  ○ Gating approaches:
		• Operating system: 64-bit Ubuntu Linux
		• Static listmode data acquisition in 3D mode
		• PET Reconstruction:
		  ○ Iterative: Ordered Subset Expectation Maximization (OSEM)
		• Attenuation correction hybrid approach:
		  ○ DIXON+bone sequence (MR-based subject attenuation correction) plus CT-based hardware attenuation correction
		• Scatter correction: Single Scatter Simulation and Relative Scaling
		• Calibration includes generation of crystal, energy, activity, and timing calibration as well as normalization factors
			Equivalent

Characteristic	Predicate Device Siemens Biograph mMR with syngo MR E11P system software (K163234)	Proposed Device Cubresa BrainPET	Equivalence Comparison
	optimal respiratory gating ○ multi-phase respiratory gating • Calibration includes generation of crystal, energy and activity calibration and normalization factors • Export of PET raw data (sinogram, list mode, normalization and physio files) Output PET images are DICOM-compliant	Output PET images are DICOM-compliant	
MR-related	Siemens syngo software is used for all MR data acquisition and processing	Siemens syngo software is used for all MR data acquisition and processing	Same
Safety			
Electrical safety	IEC 60601-1 compliance	IEC 60601-1 compliance	Same
EMC	IEC 60601-1-2 compliance	IEC 60601-1-2 compliance	Same
MRI Coil Safety and Performance	IEC 60601-2-33 compliance	ISO 10993-1 compliance	Same
Biocompatibility	ISO 10993-1 compliance	IEC 60601-1 compliance	Same
Sterility & Reprocessing	Instructions for cleaning/reprocessing are in the operator manual	Instructions for cleaning/reprocessing are in the operator manual	Same

The Cubresa BrainPET conforms to the FDA recognized consensus standards listed in Table 2.

Table 2 – FDA Recognized Consensus Standards

Recognition Number	Product Area	Standard Designation Number and Date	Title of Standard	Standards Development Organization
5-125	General I (QS/ RM)	ANSI AAMI ISO 14971:2019	Medical devices - Application of risk management to medical devices	ANSI AAMI ISO
19-46	General II (ES/ EMC)	ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010 /(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	ANSI AAMI
19-36	General II (ES/ EMC)	60601-1-2:2014 [Including AMD 1:2021]	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	ANSI AAMI IEC
13-79	Software/ Informatics	62304:2006/A1:2016	Medical device software - Software life cycle processes	ANSI AAMI IEC
12-295	Radiology	60601-2-33 Ed. 3.2 b:2015	Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	IEC
12-382	Radiology	NEMA NU 2-2024	Performance Measurements of Positron Emission Tomographs	NEMA
2-258	Biocompatibility	AAMI ANSI ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: evaluation and testing within a risk management process	AAMI ANSI ISO

VII. PERFORMANCE TESTING

The Cubresa BrainPET has been designed to provide MR and PET imaging in the same manner as the predicate Siemens Biograph mMR with syngo software (K163234). CUBRESA performed testing according to the applicable guidance and regulatory standards to demonstrate that the Cubresa BrainPET diagnostic imaging features are substantially equivalent to features of the predicate Siemens Biograph mMR with syngo software. The Cubresa BrainPET does not raise any new safety or effectiveness issues related to the use with the MRI system. No clinical testing was required to demonstrate substantial equivalence. Sample clinical images were assessed and provided as required by the guidance document Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices. The Cubresa BrainPET has passed performance testing and met product specifications. CUBRESA performed non-clinical testing which is summarized in **Table 3** .

Table 3 – Non-Clinical Testing

Testing Performed	Tested Hardware	Source/ Rationale for Test
Non-clinical Performance Testing	Cubresa BrainPET (finished device)	*Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices*
Sample Clinical Images	Cubresa BrainPET (finished device)	*Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices*
Electrical, mechanical, structural, and related system safety	Cubresa BrainPET (finished device)	ANSI /AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], ASTM F2213-25, ASTM F2052-21
Electromagnetic compatibility	Cubresa BrainPET (finished device)	IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION
Software	Cubresa BrainPET (finished device)	*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*
Cybersecurity	Cubresa BrainPET (finished device)	*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions*

Cubresa has conducted and submitted the results of a comprehensive series of non-clinical tests. These evaluations were designed to verify and validate the device's safety performance, and MRI environment compatibility in accordance with applicable standards and FDA guidance documents. The following non-clinical tests were conducted or referenced:

1. Electrical Safety and Electromagnetic Compatibility (EMC):

Electrical Safety and Electromagnetic Compatibility testing of the Cubresa BrainPET System was conducted by an independent 3rd party test lab, and confirmed compliance with the following standards:

- IEC 60601-1:2005 / A1:2012 / A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-2:2014 / A1:2020 (Ed 4.1) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

2. Software Verification and Validation:

Software verification and validation was performed in accordance with internal company processes which follow IEC 62304:2006 Medical device software — Software life cycle processes. Documentation is provided as recommended by the FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions" (CDRH, June 2023).

3. Cybersecurity

Cybersecurity testing was performed by an independent 3rd party test lab, and the documentation as recommended by the FDA's Guidance for Industry and FDA Staff, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" (CDRH, June 27, 2025) is provided.

4. Performance Bench Testing:

Performance characteristics recommended in the FDA's Guidance for Industry "Guidance for the Submission of Premarket Notifications for Emission Computed Tomography Devices and Accessories (SPECT and PET) and Nuclear Tomography Systems" IX.C.2 (CDRH,1998) were evaluated on the Cubresa BrainPET System by Cubresa Inc., and supporting documentation has been provided.

The following performance characteristics, as specified in NEMA NU 2-2018: Performance Measurements of Positron Emission Tomography, were measured in accordance with the standard under two configurations: (1) PET-only mode (with no MRI sequences running) and (2) simultaneous PET/MR mode (with an MR protocol running). The measured characteristics include:

Purpose	Methodology	Outcome
Spatial Resolution	NEMA NU2-2018 (Section 3). Measures intrinsic spatial resolution of the scanner using a point or line source of ^{18}F at varying distances from the center of the field-of-view (FOV). Results are reported as Full Width at Half Maximum (FWHM) and Full Width at Tenth Maximum (FWTM).	Pass- The test results meet the Cubresa BrainPET requirements.

Scatter Fraction, Losses, and Randoms (Count Rate Performance)	NEMA NU2-2018 (Section 4, Method 1). Uses a specialized cylindrical polyethylene phantom. Cubresa designed a modified phantom with an outer diameter of 177.8mm and is curved at the back of the phantom to fit with the curved helmet shape of the Cubresa BrainPET Tx/Rx Array.	Pass- The test results meet the Cubresa BrainPET requirements.
Sensitivity	NEMA NU2-2018 (Section 5). Evaluates the scanner's efficiency by measuring count rates from a line source surrounded by varying thicknesses of metal sleeves (simulating different levels of attenuation). Sensitivity phantom modified for Cubresa BrainPET FOV.	Pass- The test results meet the Cubresa BrainPET requirements.
Image Quality, Accuracy of Corrections	NEMA NU2-2018 (Section 7). Employs a phantom containing background and hot/cold spheres to simulate clinical conditions like whole-body lesion detection, testing the accuracy of scatter and attenuation corrections. IQ Phantom spherical array per NEMA specification, modified tank body (no lung insert), scaled to fit within Cubresa BrainPET FOV.	Pass- The test results meet the Cubresa BrainPET requirements.

5. MRI Compatibility Testing:

For use in conjunction with the Biograph mMR, the Cubresa BrainPET System was evaluated in accordance with the FDA's Guidance for Industry and FDA Staff, "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" (CDRH, 2023). Supporting documentation is provided. This evaluation included:

Purpose	Methodology	Outcome
Specific Absorption Rate (SAR) characterization	Surface temperature measurements and specific absorption rate (SAR) evaluations were conducted in accordance with NEMA MS 8-2016 Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems, Section 3 Method.	Pass- The test results meet the Cubresa BrainPET requirements.

Device Function and PET Performance in MRI Environment	The Cubresa BrainPET System's performance in the MRI environment was assessed to ensure it maintained functionality and met key performance characteristics, as defined in NEMA NU 2-2018.	Pass- The test results meet the Cubresa BrainPET requirements.
MRI Performance Assessment	MRI-related performance was evaluated through measurements of RF noise, main magnetic field homogeneity, and RF field homogeneity. Additionally, signal-to-noise ratio (SNR) and uniformity were measured and characterized using methods NEMA MS1-2008 (R2014) Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging and NEMA MS3-2008 (R2014) Determination of Image Uniformity in Diagnostic Magnetic Resonance Images, respectively, in accordance with NEMA MS 9-2008 (R2014) Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images.	Pass- The test results meet the Cubresa BrainPET requirements.
RF Noise Measurement	NSD, Siemens RF Noise Spectrum Analysis. Performed during simultaneous PET/MR acquisition.	Pass- The test results meet the Cubresa BrainPET requirements.
B0 Homogeneity evaluation	B0 homogeneity analysis performed via Siemens rf_field scan, interference lines analysis. Performed during simultaneous PET/MR acquisition.	Pass- The test results meet the Cubresa BrainPET requirements.
B1 Homogeneity evaluation	B1 homogeneity measurements performed via Siemens rf_field scan, RF field symmetry analysis. Performed during simultaneous PET/MR acquisition.	Pass- The test results meet the Cubresa BrainPET requirements.
Signal-to-Noise (SNR) evaluation	NEMA MS1-2008 (R2014). Determination of Signal-to-Noise (SNR) in Diagnostic Magnetic resonance images.	Pass- The test results meet the Cubresa

	Performed during simultaneous PET/MR acquisition.	BrainPET requirements.
Image Uniformity	NEMA MS3-2008 (R2014) Determination of Image Uniformity in Diagnostic Magnetic Resonance Images. PIU analysis. Performed during simultaneous PET/MR acquisition.	Pass- The test results meet the Cubresa BrainPET requirements.
Magnetically Induced Torque on Cubresa BrainPET in the Magnetic Resonance Environment	ASTM F2213-25 - Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	Pass- The test results meet the Cubresa BrainPET requirements.
Measurement of Magnetically Induced Displacement Force on Cubresa BrainPET in the Magnetic Resonance Environment	ASTM F2052-21 - Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	Pass- The test results meet the Cubresa BrainPET requirements.

6. Biocompatibility Testing:

Biocompatibility testing of patient-contacting materials was conducted in accordance with ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and included evaluations for cytotoxicity, sensitization, and irritation.

7. Clinical Images:

Documentation is provided regarding the clinical effectiveness of Cubresa BrainPET PET/MR images as recommended by the FDA's Guidance for Industry "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) and Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices (CDRH, Oct 2023).

Cubresa BrainPET PET and MR images acquired simultaneously in patient volunteers were evaluated by dual-trained American Board of Radiologists/Nuclear Medicine certificated physicians who have attested to the diagnostic image quality achieved by the Cubresa BrainPET PET/MR system.

8. Summary of Performance Testing:

The Cubresa BrainPET has been tested and the conclusions from the verification and validation data support that the technological characteristics of the proposed device have an equivalent safety and performance profile to the predicate device. Successful completion of the standard QA

tests and expert review of sample clinical images demonstrate that the Cubresa BrainPET maintains clinically acceptable MR imaging performance. The Cubresa BrainPET technological characteristics do not raise different questions of safety and effectiveness. The verification and validation testing of the Cubresa BrainPET supports a determination of substantial equivalence.

VIII. CONCLUSIONS

The Cubresa BrainPET has the same intended use and similar basic technological characteristics as the Siemens Biograph mMR with syngo software (K163234, predicate device). While there are some differences in technological characteristics between the proposed and predicate device, the differences were tested, and verification and validation data suggest that the features bear an equivalent safety and performance profile to that of the predicate device.

CUBRESA has concluded that the Cubresa BrainPET is substantially equivalent to the currently marketed predicate device Siemens Biograph mMR with syngo software.