



December 29, 2025

Mediso Medical Imaging Systems, Ltd.
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K253844

Trade/Device Name: AnyScan 3.0 NM Scanner Family
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: Class II
Product Code: KPS JAK
Dated: December 1, 2025
Received: December 2, 2025

Dear Prithul Bom:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

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

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See

the DICE website (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Digitally signed by Michael D.

O'hara -S

Date: 2025.12.30 09:34:22 -05'00'

For

Lora Weidner, 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

Submission Number (if known)

Device Name

AnyScan 3.0 NM Scanner Family

Indications for Use (Describe)

The AnyScan 3.0 NM Scanner Family is intended for use by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and restaging of lesions, tumors, disease and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The images produced by the system can also be used by the physician to aid in radiotherapy treatment planning or additional uses.

SPECT: The SPECT subsystem is intended to provide projection and cross-sectional images through computer reconstruction of the data, representing radioisotope distribution in the patient body or in a specific organ using planar and tomographic scanning modes for isotopes with energies up to 588 keV.

CT: CT component is intended to provide cross sectional images of the body by computer reconstruction of x-ray transmission data providing anatomical information.

PET: The PET component is intended to provide cross-sectional images representing the distribution of tomographic scanning modes.

SPECT+CT: The SPECT and CT components used together acquire SPECT/CT images. The SPECT images can be corrected for attenuation with the CT images, and can be combined (image registration) to merge the patient's physiological (SPECT) and anatomical (CT) images.

PET+CT: The PET and CT components used together acquire PET/CT images. The PET images can be corrected for attenuation with the CT images, and can be combined (image registration) to merge the patient's physiological (PET) and anatomical (CT) images.

The system maintains independent functionality of the SPECT, CT and PET components, allowing for single modality SPECT, CT and/ or PET diagnostic imaging.

Software: The Nucline software is an acquisition, display and analysis package intended to aid the clinician to extract diagnostic information supported by image assessment tools, image enhancement features and image quantification of pathologies in images produced from SPECT, CT, PET and other imaging modalities.

This CT system can be used for low dose lung cancer screening in high risk populations.*

*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

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)

AnyScan 3.0 NM Scanner Family 510(k) Summary

Submitter / Applicant

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Date: 4 December 2024

Preparer/Consultant

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Device Classification

Trade/Model Names: AnyScan 3.0 NM Scanner Family

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

Regulation Name: Computed tomography x-ray system.
Regulation Number: 21 CFR 892.1750
Secondary Product Code: JAK
Classification Name: System, tomography, computed, emission
Regulatory Class: II
510k Review Panel: Radiology

AnyScan 3.0 NM Scanner Family 510(k) Summary

Predicate Devices

	Primary Predicate Device	Secondary Predicate Device
Trade name:	Symbia 6.7 (Family)	Biograph Horizon (PET/CT)
Manufacturer:	Siemens Medical Solutions USA, Inc	Siemens Medical Solutions USA, Inc.
510(k) Clearance:	K200474	K193178
Regulation Number:	21 CFR 892.1200	21 CFR 892.1200
Regulation Name:	Emission computed tomography system	Emission computed tomography system
Regulatory Class:	Class II	Class II
Product Code:	KPS, JAK	KPS, JAK

This predicate has not been subject to a design-related recall.

Device Description

The AnyScan 3.0 NM Scanner Family will enable clinicians to utilize the device to perform separate studies in SPECT-CT, PET-CT, SPECT, PET and multi-slice CT modalities.

The AnyScan 3.0 NM Scanner Family includes the following products:

AnyScan 3.0 NM Scanner Family		
Systems	Product Names	Detector Descriptions
SPECT	AnyScan DUO-Thera SPECT	XT-94/15.9 detector
	AnyScan DUO SPECT	UHP-60/9.5 detector
	AnyScan TRIO SPECT	
SPECT/CT	AnyScan DUO SPECT/CT	UHP-60/9.5 detectors
	AnyScan TRIO SPECT/CT	
	AnyScan TRIO-IQMAX SPECT/CT	MAX-123/9.5 detector
	AnyScan TRIO-TheraMAX SPECT/CT	MAX-123/15.9 detector
SPECT/CT/PET	AnyScan DUO SPECT/CT/PET	UHP-60/9.5 detectors
	AnyScan TRIO SPECT/CT/PET	
	AnyScan TRIO-IQMAX SPECT/CT/PET	MAX-123/9.5 detector
	AnyScan TRIO-TheraMAX SPECT/CT/PET	MAX-123/15.9 detector
PET/CT	AnyScan PET/CT	PET and CT detectors

AnyScan 3.0 NM Scanner Family

510(k) Summary

The partial product names 'TRIO' and 'DUO' only differentiate the number of built-in SPECT detectors.

The partial product names 'IQMAX' and 'TheraMAX' only differentiate the type of built-in SPECT detector. The SPECT gamma camera generates nuclear medicine images based on the uptake of radioisotope tracers in a patient's body, and supports integration with CT's anatomical detail for precise reference of the location of the metabolic activity.

The CT component produces cross-sectional images of the body by computer reconstruction of x-ray transmission data from either the same axial plane taken at different angles or spiral planes taken at different angles.

The PET component images and measures the distribution of PET radiopharmaceuticals in humans for the purpose of determining various metabolic (molecular) and physiologic functions within the human body and utilizes the CT for fast attenuation correction maps for PET studies and precise anatomical reference for the fused PET and CT images.

The combination of SPECT, CT, and PET in a single device has several benefits. The SPECT subsystem images biochemical function while the CT subsystem images anatomy. The combination enables scans that not only indicate function, e.g., how active a tumor is, but precise localization, e.g., the precise location of that tumor in the body.

Combined SPECT and CT subsystems are intended for SPECT imaging enhanced with spatially registered CT image-based corrections, anatomical localization of tracer uptake and anatomical mapping. CT can be used to correct for the attenuation in SPECT acquisitions. Attenuation in SPECT is an unwanted side effect of the gamma rays scattering and being absorbed by tissue. This can lead to errors in the final image. The CT directly measures attenuation and can be used to create a 3D attenuation map of the patient which can be used to correct the SPECT images. The SPECT-CT scanner can be used to image and track how much dose was delivered to both the target and the surrounding tissue. The system maintains independent functionality of the CT and SPECT subsystems.

Combined PET and CT subsystems are intended for PET imaging enhanced with spatially registered CT image-based corrections, anatomical localization of tracer uptake and anatomical mapping. system maintains independent functionality of the CT and PET subsystems, allowing for single modality CT and/or PET diagnostic imaging.

A patient positioning light marker is generated by a low-power (Class II per IEC 60825-1) red laser. NuLine software is installed on acquisition workstation to perform patient management, data management, scan control, image reconstruction and image archival and evaluation. All images conform to DICOM imaging format requirements.

The systems also include display equipment, data storage devices, patient and equipment supports, software, and accessories.

InterView XP; InterView FUSION (K221984) and software is integrated for DICOM image visualization and post-processing.

ClariCT (K212074) software is integrated for DICOM CT de-noising.

Indications for Use

The AnyScan 3.0 NM Scanner Family is intended for use by appropriately trained health care professionals to aid in detecting, localizing, diagnosing, staging and restaging of lesions, tumors,

AnyScan 3.0 NM Scanner Family 510(k) Summary

disease and organ function for the evaluation of diseases and disorders such as, but not limited to, cardiovascular disease, neurological disorders and cancer. The images produced by the system can also be used by the physician to aid in radiotherapy treatment planning or additional uses.

- The SPECT subsystem is intended to provide projection and cross-sectional images through computer reconstruction of the data, representing radioisotope distribution in the patient body or in a specific organ using planar and tomographic scanning modes for isotopes with energies up to 588 keV.
- CT component is intended to provide cross sectional images of the body by computer reconstruction of xray transmission data providing anatomical information.
- The PET component is intended to provide cross- sectional images representing the distribution of tomographic scanning modes.
- The SPECT and CT components used together acquire SPECT/CT images. The SPECT images can be corrected for attenuation with the CT images, and can be combined (image registration) to merge the patient's physiological (SPECT) and anatomical (CT) images.
- The PET and CT components used together acquire PET/CT images. The PET images can be corrected for attenuation with the CT images, and can be combined (image registration) to merge the patient's physiological (PET) and anatomical (CT) images.
- The system maintains independent functionality of the SPECT, CT and PET components, allowing for single modality SPECT, CT and/ or PET diagnostic imaging.
- Software: The NuLine software is an acquisition, display and analysis package intended to aid the clinician to extract diagnostic information supported by image assessment tools, image enhancement features and image quantification of pathologies in images produced from SPECT, CT, PET and other imaging modalities.
- This CT system can be used for low dose lung cancer screening in high risk populations.*

*As defined by professional medical societies. Please refer to clinical literature, including the results of the National Lung Screening Trial (N Engl J Med 2011; 365:395-409) and subsequent literature, for further information.

Comparison of Technological Characteristics with The Predicate Device

AnyScan 3.0 NM Scanner Family is similar in materials, energy source, or technological characteristics when compared to the predicate devices. Both the subject device and predicate devices are SPECT, CT, PET scanners that support various visualization and evaluation tools. The intended use and fundamental scientific technology are similar to the predicate devices; therefore, Mediso believes that they are substantially equivalent to the predicate devices.

Performance data

The following performance data were provided in support of the substantial equivalence determination.

1.1 SPECT Performance

AnyScan 3.0 conforms to the NEMA NU 1-2018 international standard, which describes the performance of SPECT devices. ^{99m}Tc isotope measurements unless other isotope specified.

The predetermined acceptance values between the subject and predicate device are similar. There is no impact on safety and effectiveness.

All performance testing of the subject device met the predetermined acceptance values.

AnyScan 3.0 NM Scanner Family 510(k) Summary

1.1.1 Comparison of SPECT Performance with 3/8" (9.5 mm) detector

SPECT Performance Criteria	Acceptance values		
	<u>Subject device</u> AnyScan 3.0 NM Scanner Family with TRIO-IQMAX MAX- 123/9.5 detector (3/8" crystal, 123 pcs PMT)	<u>Subject device</u> AnyScan 3.0 NM Scanner Family with UHP-60/9.5 detector (3/8" crystal, 60 pcs PMT)	<u>Predicate device</u> Symbia 6.7 3/8" detector (3/8" crystal, 59 pcs PMT)
Intrinsic Spatial Resolution			
FWHM in CFOV	≤2.6 mm	≤3.4 mm	≤3.8 mm
FWHM in UFOV	≤2.7 mm	≤3.5 mm	≤3.9 mm
FWTM in CFOV	≤5.1 mm	≤6.6 mm	≤7.5 mm
FWTM in UFOV	≤5.3 mm	≤6.8 mm	≤7.7 mm
Intrinsic Spatial Linearity			
Differential in CFOV	≤0.10 mm	≤0.17 mm	≤0.2 mm
Differential in UFOV	≤0.10 mm	≤0.18 mm	≤0.2 mm
Absolute in CFOV	≤0.20 mm	≤0.30 mm	≤0.4 mm
Absolute in UFOV	≤0.22 mm	≤0.36 mm	≤0.7 mm
Intrinsic Energy Resolution			
FWHM in CFOV	≤9.3%	≤9.5%	≤9.9%
Intrinsic Flood Field Uniformity (Uncorrected)			
Differential in CFOV	≤1.8 %	≤2.0 %	≤2.5 %
Differential in UFOV	≤1.9 %	≤2.2 %	≤2.7 %
Integral in CFOV	≤2.2 %	≤2.5 %	≤2.9 %
Integral in UFOV	≤2.6 %	≤3.3 %	≤3.7 %
Multiple Window Spatial Registration	≤0.6 mm	≤0.6 mm	≤0.6 mm
Intrinsic Count Rate Performance in Air			
Maximum Count Rate @20% window	≥600 kcps	≥600 kcps	≥310 kcps
System Spatial Resolution Without Scatter (at 10 cm)	LEHR-HS		LEHR
FWHM in CFOV	≤7.3 mm	≤7.4 mm	≤7.5 mm
FWTM in CFOV	≤13.2 mm	≤13.4 mm	≤13.6 mm
System Spatial Resolution with Scatter (at 10 cm)	LEHR-HS		LEHR
FWHM in CFOV	≤8.0 mm	≤8.1 mm	≤8.3 mm
FWTM in CFOV	≤18.5 mm	≤19.1 mm	≤18.6 mm
System Planar Sensitivity (at 10 cm)	LEHR-HS		LEHR
Absolute	220 cpm/μCi	220 cpm/μCi	202 cpm/μCi
System volume sensitivity	LEHR-HS		LEHR
Sensitivity per axial centimeter (VSAC) (Dual-Head/Triple-Head system)	≥ -/36.0 (kcts/sec)/(MBq/cm ²)	≥ 24.0/36.0 (kcts/sec)/(MBq/cm ²)	12.0/No triple-head system is available (kcts/sec)/ (MBq/cm ²)
Detector-Detector Sensitivity Variation	≤4.0%	≤5.0%	≤5.0 %

AnyScan 3.0 NM Scanner Family 510(k) Summary

SPECT Performance Criteria	Acceptance values		
	<u>Subject device</u> AnyScan 3.0 NM Scanner Family with TRIO-IQMAX MAX- 123/9.5 detector (3/8" crystal, 123 pcs PMT)	<u>Subject device</u> AnyScan 3.0 NM Scanner Family with UHP-60/9.5 detector (3/8" crystal, 60 pcs PMT)	<u>Predicate device</u> Symbia 6.7 3/8" detector (3/8" crystal, 59 pcs PMT)
Reconstructed spatial resolution with scatter at FBP/ Iterative reconstruction SW	LEHR-HS		LEHR
Center	≤9.6/4.5 mm	≤9.9/4.6 mm	≤10.7/5.8 mm
Radial	≤10.2/4.3 mm	≤10.2/4.5 mm	≤10.9/5.0 mm
Tangential	≤6.8/3.1 mm	≤7.1/3.4 mm	≤7.9/4.1 mm

AnyScan 3.0 NM Scanner Family 510(k) Summary

1.1.2 Comparison of SPECT Performance with 5/8" (15.9 mm) detector

SPECT Performance Criteria	Acceptance values	
	<u>Subject device</u> AnyScan 3.0 NM Scanner Family with TRIO TheraMAX MAX-123/15.9 mm detector (5/8" crystal thickness, 123 pcs PMT)	<u>Predicate device</u> Symbia 6.7 5/8" detector (5/8" crystal thickness, 59 pcs PMT)
Intrinsic Spatial Resolution		
FWHM in CFOV	≤3.3 mm	≤4.5 mm
FWHM in UFOV	≤3.4 mm	≤4.6 mm
FWTM in CFOV	≤6.5 mm	≤8.7 mm
FWTM in UFOV	≤6.6 mm	≤8.9 mm
Intrinsic Spatial Linearity		
Differential in CFOV	≤0.10 mm	≤0.2 mm
Differential in UFOV	≤0.10 mm	≤0.2 mm
Absolute in CFOV	≤0.20 mm	≤0.5 mm
Absolute in UFOV	≤0.22 mm	≤1.0 mm
Intrinsic Energy Resolution		
FWHM in CFOV	≤9.3%	≤9.9%
Intrinsic Flood Field Uniformity (Uncorrected)		
Differential in CFOV	≤1.8 %	≤2.5 %
Differential in UFOV	≤1.9 %	≤2.7 %
Integral in CFOV	≤2.2 %	≤2.9 %
Integral in UFOV	≤2.6 %	≤3.7 %
Multiple Window Spatial Registration	≤0.6 mm	≤1.0 mm
Intrinsic Count Rate Performance in Air		
Maximum Count Rate @20% window	≥600 keps	≥460 keps
Intrinsic Spatial Resolution at 75 keps		
FWHM in UFOV	≤3.4 mm	≤4.6 mm
FWTM in UFOV	≤6.6 mm	≤8.9 mm
System Spatial Resolution Without Scatter (at 10 cm)	LEHR-HS	LEHR
FWHM in CFOV	≤7.4 mm	≤7.8 mm
FWTM in CFOV	≤13.4 mm	≤14.9 mm
System Spatial Resolution With Scatter (at 10 cm)	LEHR-HS	LEHR
FWHM in CFOV	≤8.1 mm	≤8.9 mm
FWTM in CFOV	≤19.1 mm	≤19.5 mm
System Planar Sensitivity (at 10 cm)	LEHR-HS	LEHR
Absolute	244 cpm/μCi	225 cpm/μCi
Reconstructed spatial resolution with scatter at FBP	LEHR-HS	LEHR
Center	≤9.9 mm	≤11.5 mm
Radial	≤10.2 mm	≤12.0 mm
Tangential	≤7.1 mm	≤8.8 mm

AnyScan 3.0 NM Scanner Family 510(k) Summary

1.2 CT performance

The performance values between the subject and predicate device are similar. There is no impact on safety and effectiveness.

All performance testing of the subject device met the performance criteria.

CT Performance Criteria	Subject Device AnyScan 3.0 NM Scanner Family	Reference Device Symbia Intevo Bold (K162483)
Acquired/Reconstructed CT slice/rot.	16/32	16/32
Min. rotational time (sec)	0.5	0.5
Min. full (360*) scan time (sec)	0.5	0.5
Min. partial (240*) scan time (sec)	0.33	0.33
Max. z-coverage (mm)	20	19.2
Min. slice thickness (mm)	0.625	0.6
Tube min. current (mA)	10	25
Min. current-exposure time @360* (mAs)	5	12.5
Min. current-exposure time @240* (mAs)	3.3	8.25
Tube max. current (mA)	440	345
X-Ray generator power (kW)	60	50
Tube anode heat storage (MHU)	7.5	5
Tube min.-max. current (mA)	10-440	25-345
High Power CT Imaging	80kV: 440mA 100kV: 440mA 120kV: 440mA 140kV: 380mA	80, 110, 130 kV 25 - 345 mA
Single breath-hold im. (400 mm) time(sec)	5.5	5.2
High-contrast res. @ 2% MTF (lp/cm) (±10%)	15.9	15.8
Helical & continuous scan length (mm)	1920	1860
High Voltage KVpp range	80, 100, 120, 140	80, 110, 130
Bore size (cm)	70	70
Generator Output	53.2 kW	50kW
# Elements	24 x 896	24 x 1472
Topogram (Length x Scan Field)	100-2000 x 500mm	128 -1530 x 500 mm
LC Resolution (20cm Catphan / CTDIvol 32cm)	3.0 mm/ 2.9HU / 13.60 mGy	5 mm/3HU/12.88 mGy
CTDI (Dose/100 mAs) / 16cm Phant. (typical head) 32cm Phant. (typical body)	Typical head: 120keV Center: 14.0 mGy Surface: 14.2 mGy Typical body: 120keV Center: 4.7 mGy Surface: 8.4 mGy	Typical head: 130 kV A: 18.7 mGy B: 19.6 mGy Typical body: 130 kV A: 5.8 mGy B: 10.9 mGy
Max. HC Resolution (2% MTF wire in plastic)	15.16 lp/cm	15.15 lp/cm
Max. scan range // Max. Scantime	202 cm // 120 s	157 cm // 100 s

AnyScan 3.0 NM Scanner Family 510(k) Summary

1.3 PET performance

AnyScan 3.0 conforms to NEMA NU 2-2018 international standard, which describes the performance of PET devices. 18F isotope measurements unless otherwise indicated.

The performance values between the subject and predicate device are similar. There is no impact on safety and effectiveness.

All performance testing of the subject device met the predetermined acceptance values.

PET Performance Criteria	Acceptance values	
	Subject device AnyScan 3.0 NM Scanner Family	Predicate device Biograph Horizon PET/CT (K193178)
Resolution – Full size		
Transverse Resolution FWHM @ 1 cm	<5.2 mm	≤ 4.7 mm
Transverse Resolution FWHM @ 10 cm	<5.5 mm	≤ 5.5 mm
Transverse Resolution FWHM @ 20 cm	<6.4 mm	≤ 7.6 mm
Axial Resolution FWHM @ 1 cm	<4.9 mm	≤ 5.0 mm
Axial Resolution FWHM @ 10 cm	<5.0 mm	≤ 7.0 mm
Axial Resolution FWHM @ 20 cm	<6.2 mm	≤ 11.3 mm
Sensitivity / Scatter / Bias		
Sensitivity @435 keV LLD	5.0 cps/kBq	≥ 5.8 cps/kBq
Scatter Fraction at peak NECR	≤ 44%	≤ 40%
Mean bias (%) at peak NEC	≤ +/- 6%	≤ +/- 6%
Image Quality (4 to 1) - (% Contrast / Background Variability)		
10mm sphere	≥15% / <9%	≥ 10% / ≤ 10%
13mm sphere	≥30% / <8%	≥ 25% / ≤ 10%
17mm sphere	≥35% / <7%	≥ 40% / ≤ 10%
22mm sphere	≥50% / <7%	≥ 55% / ≤ 10%
28mm sphere	≥70% / <5%	≥ 60% / ≤ 10%
37mm sphere	≥85% / <5%	≥ 65% / ≤ 10%
Co-Registration Accuracy		
Max Error	≤ 4 mm	≤ 5 mm

1.4 Safety and effectiveness

Safety and effectiveness of the **AnyScan 3.0 NM Scanner Family** device was further documented by the following:

The device labeling contains instructions for use and any necessary cautions and warnings to provide for safe and effective use of the device.

Regarding Biocompatibility, the patient-contacting components are evaluated according to ISO 10993-1.

Regarding the Software, the software verification report is according to IEC 62304.

Regarding Risk Management, the risk management report was completed according to ISO 14971.

AnyScan 3.0 NM Scanner Family 510(k) Summary

AnyScan 3.0 NM Scanner Family conforms to applicable FDA recognized and international IEC, ISO and NEMA standards with regards to performance and safety as required by the respective SPECT FDA Guidance Documents. SPECT detector and CT performance is conducted according to NEMA NU1-2018, and PET detector performance is conducted according to NEMA NU2-2018. The performance is similar to the predicate devices.

Regarding Electromagnetic Compatibility, the tests were completed according to IEC 60601-1-2. The device passed these tests to the IEC standard.

Regarding Electrical, Mechanical and Thermal Safety, the tests were completed according to IEC 60601-1 and IEC 62366-1. The device passed these tests to the IEC standards.

Regarding Performance Testing, the performance tests were completed for SPECT according to NEMA NU 1-2018 and for PET according to NEMA NU 2-2018. The device passed these tests to the NEMA standard.

Conclusions

A comparison of the subject to a legally marketed predicate was performed to demonstrate substantial equivalence. Results of that comparison revealed the following:

1. The subject and predicate devices have similar indications for use and intended use.
2. The subject and predicate devices have similar technological characteristics, with only minor differences that do not raise different questions of safety and effectiveness.
3. Tests based on consensus industry standards confirmed the performance capabilities of the subject device.

The comparison analysis and performance test results demonstrate the subject device is **at least as safe and effective** as the legally marketed predicate. Furthermore, this finding of **substantial equivalence** warrants clearance for marketing activities.

In conclusion, **AnyScan 3.0 NM Scanner Family** is substantially equivalent to the legally marketed **Symbia 6.7** and **Biograph Horizon**, and thus warrants clearance from FDA for marketing activities in the United States.