May 15, 2026

medXion Technologies, Inc.
% Kazuhito Tomii
CEO
2-12-27 Kodo
Adachi-Ku
TOKYO, 1200013
JAPAN

Re: K253935
Trade/Device Name: medXion NEXUS
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-Ray System
Regulatory Class: Class II
Product Code: OAS
Dated: December 1, 2025
Received: April 13, 2026

Dear Kazuhito Tomii:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
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)*
K253935

Device Name
medXion NEXUS

Indications for Use *(Describe)*
MedXion NEXUS is intended to produce three-dimensional digital X-ray images of the dental, oral, maxillofacial region, and ENT (Ear, Nose and Throat) and neck region at the direction of healthcare professionals as diagnostic support for adult and pediatric patients.

This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old. Use of equipment and exposure settings designed for adults of average size can result in excessive radiation exposure for a smaller patient. Studies have shown that pediatric patients may be more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher), and so unnecessary radiation exposure is of particular concern for pediatric patients.

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.

510(k) Summary

Device Name: medXion NEXUS

K253935

1. **Submission Sponsor**

medXion Technologies Inc.
2-12-27 Kodo,
Adachi-ku Tokyo 1200013
Japan
Kazuhito Tomii
CEO
Email: tomii@medxion.co.jp
Office number: +81-5010557778

2. **Submission Correspondent**

Same as above

3. **Date Prepared**

2026-5-13

4. **Device Identification**

Product/Trade Name: medXion NEXUS

Common Name: Computed Tomography X-ray System

Classification Name: Computed Tomography X-ray System

Classification Panel: Radiology

Regulation Number: 21 CFR §892.1750

Device Class: Class II

Product Code: OAS

5. Legally Marketed Predicate Device(s) and Reference Device

Predicate Device:
Product/Trade Name: PreXion3D Explorer EX
510(K) Number: K193329
Common Name: Computed Tomography X-ray System
Classification Name: Computed Tomography X-ray System
Classification Panel: Radiology
Regulation Number: 21 CFR §892.1750
Device Class: Class II
Product Code: OAS

6. Indication for Use Statement

MedXion NEXUS is intended to produce three-dimensional digital X-ray images of the dental, oral, maxillofacial region, and ENT (Ear, Nose and Throat) and neck region at the direction of healthcare professionals as diagnostic support for adult and pediatric patients.

This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year old. Use of equipment and exposure settings designed for adults of average size can result in excessive radiation exposure for a smaller patient. Studies have shown that pediatric patients may be more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher), and so unnecessary radiation exposure is of particular concern for pediatric patients.

7. Device Description

medXion NEXUS consists of a scanner, which is used for generating X-ray and detecting image data, and a Console, which is used for operating the scanner and managing the data. The scan data acquired by the scanner will be transferred to the Console. medXion NEXUS Image Analysis System will then perform the image analysis or image edition (creating cross-section diagram, etc.), and output the image to a printer.

X-ray image data is acquired while the rotation arm is rotating around the secured “patient’s head” at a constant speed. X-rays, which are emitted from X-ray generator (built in one side of rotation arm), pass through a patient and are detected by the flat panel detector (built in the other side of rotation arm). The detected X-ray absorption data is used to process image reconstruction on the Console to create the 3D image (CT scan) and the tomographic image.

This device does not use patient restraints such as chin rests or headrests, as requested by the customer. Neck supports and head stabilizers are used to suppress patient movement.

As “Table-6A: Comparison of Characteristics” shows that medXion NEXUS (Device in concern) is the equivalent with the predicate device, PreXion3D Explorer EX (K193329).

8. Substantial Equivalence Discussion

The selected predicate device (K193329) has identical indications for use and utilizes the same fundamental technology as the subject device. Any minor technological differences do not raise new questions of safety or effectiveness, as demonstrated by the bench performance testing provided in this submission.

Table-6A: Comparison of Characteristics

	Subject Device	**Predicate Device**	**Comparison to predicate**
Manufacturer	**medXion Technologies Inc.**	**PreXion Corporation**	
Trade Name	***medXion NEXUS***	**PreXion3D Explorer EX**	
510(k) Number		K193329	
Product Code	OAS	OAS	Same
Regulation Number	OAS: 21 CFR 892.1750	OAS: 21 CFR 892.1750	Same
Regulation Name	OAS: Computed tomography x-ray system	OAS: Computed tomography x-ray system	Same
Device Classification Name	X-Ray, Tomography, Computed, Dental	X-Ray, Tomography, Computed, Dental	Same
Indications for use:	medXion NEXUS is intended to produce three-dimensional digital X-ray images of the dental, oral, maxillofacial region, and ENT (Ear, Nose and Throat) and neck region at the direction of healthcare professionals as diagnostic support for adult and pediatric patients. This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year-old. Use of equipment and exposure settings designed for adults of average size can result in excessive radiation exposure for a smaller patient. Studies have shown that pediatric patients may be more radiosensitive than adults (i.e., the cancer risk per unit dose of ionizing radiation is higher), and so unnecessary radiation exposure	PreXion3D Explorer EX is intended to produce two-dimensional digital x-ray images including panoramic image, and three-dimensional digital x-ray images of the dental, oral, maxillofacial region, ENT (Ear, Nose and Throat) and neck region at the direction of healthcare professionals as diagnostic support for adult and pediatric patients. This device is not intended for use on patients less than approximately 21 kg (46 lb) in weight and 113 cm (44.5 in) in height; these height and weight measurements approximately correspond to that of an average 5 year-old. Use of equipment and exposure settings designed for adults of average size can result in excessive radiation exposure for a smaller patient. Studies have shown that pediatric patients may be more radiosensitive than adults (i.e., the	The differences in pediatric-related wording do not raise new questions of safety or effectiveness, For details, please refer to 1.

	is of particular concern for pediatric patients.	cancer risk per unit dose of ionizing radiation is higher), and so unnecessary radiation exposure is of particular concern for pediatric patients.	
Patient/User Characteristics			
Target Population	Children aged 6 (except infants) to elderly	Children aged 6 (except infants) to elderly	Same
Anatomical Site	The dental, oral, maxillofacial region ENT (Ear, Nose and Throat) and neck region	The dental, oral, maxillofacial region ENT (Ear, Nose and Throat) and neck region	Same
Users	Health care professionals	Health care professionals	Same
Technological Characteristics and Performance			
Patient Contact Material	None Patient stabilization approach without rigid fixation	CHIN REST: polycarbonate Forehead Holder: silicone rubber HANDLE GRIP: silicone rubber	Subject device has no parts come into contact with the patient. For details, please refer to 2.
Sterility	Non-sterile	Non-sterile	Same
X-ray Generator			
Tube Voltage	90-110KV	90-110KV	Same
Exposure function	Continuous	Pulsed	Lower total radiation dose compared to predicate. For details, please refer to 3.
Tube Current	1-3mA	1-5mA	Reducing the tube current reduces the radiation dose.
Focal Spot Size	0.3mm x 0.3mm	0.3mm x 0.3mm	Same
FPD Detector			
Detector	FPD (IGZO TFT)	FPD (TFT)	The sensitivity has been improved.
***P*ixel Size**	560 μm x 560μm (With 4x4binning) 280 μm x 280μm (With 2x2binning) 140 μm x140μm (Without binning)	248 μm x248μm (With 2x2 binning) 124 μm x124μm (Without binning)	The Subject Device is substantially equivalent to the Predicate Device with respect to pixel size and image resolution. For details, please refer to 4.
Pixel Number	756x756 (With 4x4 binning) 1536x1536 (With 2x2 binning) 3072x3072 (Without binning)	1024x1280(With 2x2 binning) 2560x2048(Without binning)	The Subject Device is substantially equivalent to the

			Predicate Device with respect to pixel size and image resolution. For details, please refer to 4.
Size of Active Area	430.08mm x 430.08mm	253.95mm x 317.44mm 230mm x 15mm (Panoramic)	The larger active area gives the advantage. For details, please refer to 5.
Number of Bits	16bits	16bits	Same
Scanner			
SID/SOD	800mm/ 520mm	700mm/ 420mm	The difference in SID is due to geometric balancing and does not result in differences in safety or performance. For details, please refer to 6.
Dimension (WxDxH)	1210 mm x 1247 mm x 2271 mm	880 mm x 1237 mm x 2268 mm	Differences in device shape do not affect safety or performance
Voltage	120VAC	120VAC	Same
Input	1.0 kVA	1.0 kVA	Same
3D Imaging			
Scan Time	6-16.4sec	10-20sec	The exposure time is shortened to keep the dose low.
FOV (Voxel Size)	ϕ 300mm x H300mm (0.300 - 0.500mm) ϕ 150mm x H150mm (0.150 - 0.200mm)	ϕ 150mm x H100mm (0.100 - 0.200mm) ϕ 100mm x H100mm (0.100 - 0.200mm) ϕ 50mm x H50mm(0.100 - 0.200mm)	The larger FOV than the predicate allows for greater coverage of a single scan, providing an advantage. For details, please refer to 7.
Dose Level (CTDIw)	Standard mode Conditions: 110KV/2mA/6s 30x30cm: 2.19mGy	Standard mode Conditions: 110KV/2mA/10s 15x15cm: 8.7mGy 5x5 cm: 0.9mGy	Compared to predicates, it has advantages due to its low dose. For details, please refer to 8.

	High Definition Mode Conditions: 110KV/2mA/12s 30x30cm: 4.51mGy Ultra-High Definition Conditions: 110KV/2mA/16s 30x30cm: 5.95mGy	High Definition Mode Conditions: 110KV/2mA/18s 15x15cm: 15.3mGy 5x5 cm: 1.6mGy Ultra-High Definition Conditions: 110KV/2mA/20s 15x15cm: 23.2mGy 5x5 cm: 4mGy	
Spatial Resolution	Standard mode: 50%MTF: 0.95 LP/mm 20%MTF: 2.0 LP/mm High definition mode: 50%MTF: 0.95LP/mm 20%MTF: 2.0 LP/mm Ultra High definition mode: 50%MTF: 0.95LP/mm 20%MTF: 2.0LP/mm	Standard mode: 50%MTF: 0.95LP/mm 20%MTF:2.0LP/mm High Resolution mode: 50%MTF: 0.95LP/mm 20%MTF:2.0LP/mm High contrast mode: 50%MTF: 0.95LP/mm 20%MTF:2.0LP/mm	It has the same performance as predicate.
Viewer Software (Image Analysis System Software)	Display High-resolution 2D and 3D Images Function Image Processing Function includes Airway measurement Image Operation Function Output Function	Display High-resolution 2D and 3D Images Function Image Processing Function include Airway measurement Image Operation Function Output Function	Same
Console Software System Settings	CT Scan	CT Scan include CT-Panoramic mode	Same
Applied Standard			
Electrical Safety Standard	ANSI/AAMI 60601-1 IEC60601-1-2 Ed 4.1 IEC60601-1-3 Ed 2.2 IEC60601-1-6 Ed 3.2 IEC60601-2-63 Ed 1.2 IEC62304 Ed 1.1 IEC 62366-1:2025+A1:2020 IEC61223-3-4 IEC61223-3-7 ISO 14971	ANSI/AAMI ES60601-1 IEC60601-1-2 IEC60601-1-3 IEC60601-1-6 IEC60601-2-63 IEC62304 IEC 62366 IEC61223-3-4 IEC61223-3-5 IEC60825-1 ISO 14971	Because the subject device does not use laser units, it is not subject to IEC 60825-1.

Laser Safety Standard	None	IEC 60825-1	This device does not use lasers for positioning.
DICOM Standard	NEMA PS 3.1-3.20	NEMA PS 3.1 - 3.20	Same
Biocompatibility	None	ISO 10993-1 ISO 10993-5 ISO 10993-10	No parts come into contact with the patient

The subject and predicate devices also have differences in technological characteristics, summarized as follows:

1. Indications for use

The Subject Device, medXion NEXUS, and the Predicate Device, PreXion3D Explorer EX, have the same intended use. Both devices are intended to produce three-dimensional digital X-ray images of the dental, oral, maxillofacial, ENT (ear, nose, and throat), and neck regions. Both devices are used at the direction of healthcare professionals as diagnostic support for adult and pediatric patients.

The Predicate Device includes additional descriptive language regarding minimum patient height and weight and warnings related to radiation exposure in smaller pediatric patients. The Subject Device does not include explicit numerical height or weight limitations in its Indications for Use. This difference does not represent a change in intended use or target patient population. Rather, the additional language in the Predicate Device provides precautionary and explanatory information related to known radiation safety considerations for pediatric patients.

Therefore, the differences in pediatric-related wording do not raise new questions of safety or effectiveness, and the Subject Device is substantially equivalent to the Predicate Device with respect to Indications for Use.

2. Patient Contact Material:

The Predicate Device, PreXion3D Explorer EX, includes a chin rest that may contact the patient's skin during use. The Subject Device, medXion NEXUS, does not include a chin rest and therefore does not have any direct or indirect patient-contacting components.

This difference does not affect the intended use, clinical application, or safety and effectiveness of the device. The Subject Device eliminates patient skin contact associated with a chin rest by using alternative non-contact or repositioned patient support and alignment methods. (e.g., using a chair with a backrest or headrest) As a result, the Subject Device presents an equal or lower biocompatibility risk compared to the Predicate Device.

Because the Subject Device has no patient-contacting materials, biocompatibility evaluation in accordance with ISO 10993 is not required. The absence of patient-contacting components does not introduce new risks and does not raise new questions of safety or effectiveness.

Therefore, despite the presence of a chin rest in the Predicate Device and its absence in the Subject Device, the devices are substantially equivalent with respect to patient contact materials.

3. Exposure Function

The Predicate Device utilizes a pulsed exposure function, while the Subject Device, medXion NEXUS, employs a continuous exposure mode during image acquisition. This difference represents an implementation choice in exposure control and does not change the intended use or diagnostic purpose of the device.

The Subject Device adopts continuous exposure in combination with a high-speed, high frame-rate image acquisition system. This design allows sufficient image data to be acquired within a shorter total scan time, thereby enabling the use of lower exposure per frame and reducing the need for repeated or prolonged exposures. As a result, the overall patient radiation dose can be equal to or lower than that of pulsed exposure systems designed for comparable diagnostic performance.

Therefore, the use of continuous exposure with high frame-rate imaging in the Subject Device does not raise new questions of safety or effectiveness and supports substantial equivalence to the Predicate Device with respect to the exposure function.

4. Pixel Size / Pixel Number

The Subject Device, medXion NEXUS, and the Predicate Device, PreXion3D Explorer EX, utilize digital X-ray detectors with different nominal pixel sizes and numbers. This difference reflects a design choice in detector technology and does not affect the intended use, clinical application, or diagnostic purpose of the devices.

Both devices are designed to produce diagnostically acceptable three-dimensional images of the dental, oral, maxillofacial, ENT, and neck regions. The effective spatial resolution of each system is determined by the overall imaging chain, including detector characteristics, focal spot size, system geometry, reconstruction algorithms, and image processing, rather than pixel size alone.

The Subject Device compensates for pixel size differences through system-level optimization, including detector performance, acquisition parameters, and image reconstruction methods, to achieve image quality suitable for the same diagnostic tasks as the Predicate Device. Image quality performance has been verified through appropriate bench testing and image quality evaluations, demonstrating that the Subject Device provides comparable diagnostic information.

Therefore, the difference in pixel size does not introduce new clinical indications, does not impact diagnostic performance, and does not raise new questions of safety or effectiveness. The Subject Device is substantially equivalent to the Predicate Device with respect to pixel size and image resolution.

5. Size of Active Area

The Subject Device, medXion NEXUS, utilizes a digital X-ray detector with a larger active area compared to the Predicate Device, PreXion3D Explorer EX. This difference represents a design enhancement and does not alter the intended use, diagnostic purpose, or target patient population of the device.

The larger active area of the Subject Device provides improved anatomical coverage per acquisition, which reduces the need for repositioning or repeat scans and supports efficient image acquisition. This design characteristic may improve workflow and can contribute to dose efficiency by minimizing the likelihood of additional exposures due to incomplete coverage.

Despite this difference, both devices are intended to acquire diagnostically acceptable two-dimensional and three-dimensional images of the dental, oral, maxillofacial, ENT, and neck regions. The fundamental imaging principles, X-ray generation, image acquisition, reconstruction, and display functions are comparable between the two devices.

The increased active area does not introduce new clinical indications, new imaging modes, or new user interactions. Image quality and radiation dose performance of the Subject Device have been verified through appropriate bench testing to demonstrate that it meets applicable performance and safety requirements and provides diagnostic information comparable to the Predicate Device.

Therefore, the difference in detector active area does not raise new questions of safety or effectiveness. The Subject Device is substantially equivalent to the Predicate Device with respect to detector active area.

6. SID

The Subject Device, medXion NEXUS, and the Predicate Device, PreXion3D Explorer EX, have different nominal source-to-image distances (SID). This difference reflects a system geometry design choice and does not affect the intended use, clinical application, or diagnostic purpose of the devices.

Both devices are designed to produce diagnostically acceptable three-dimensional X-ray images of the dental, oral, maxillofacial, ENT, and neck regions. The overall image quality and radiation dose performance are determined by the complete imaging system, including SID, focal spot size, detector characteristics, acquisition parameters, and image reconstruction algorithms, rather than SID alone.

The Subject Device optimizes its system geometry to balance image magnification, spatial resolution, and radiation dose. Any differences in SID are compensated through detector design, acquisition settings, and reconstruction processing to achieve image quality suitable for the same diagnostic tasks as the Predicate Device. Performance verification testing demonstrates that the Subject Device provides comparable diagnostic information.

The difference in SID does not introduce new clinical indications, new imaging modes, or new user interactions, and does not raise new questions of safety or effectiveness.

Therefore, despite differences in SID, the Subject Device is substantially equivalent to the Predicate Device with respect to imaging geometry and diagnostic performance.

7. FOV

The Subject Device, medXion NEXUS, provides a larger maximum field of view (FOV) compared to the Predicate Device, PreXion3D Explorer EX. This difference represents a design enhancement and does not change the intended use, diagnostic purpose, or target patient population of the device.

The larger FOV of the Subject Device allows broader anatomical coverage in a single acquisition, which may reduce the need for multiple scans or patient repositioning and can improve clinical workflow. This capability supports comprehensive imaging of the dental, oral, maxillofacial, ENT, and neck regions for the same diagnostic applications as the Predicate Device.

Despite the difference in maximum FOV size, both devices operate based on the same imaging principles and are intended to produce diagnostically acceptable three-dimensional X-ray images for identical clinical indications. The Subject Device does not introduce new imaging indications, new clinical applications, or new use environments as a result of the larger FOV.

Therefore, the larger FOV of the Subject Device does not raise new questions of safety or effectiveness. The Subject Device is substantially equivalent to the Predicate Device with respect to field of view.

8. Dose Level:

The Subject Device, medXion NEXUS, utilizes a higher-performance flat panel detector (FPD) compared to the detector used in the Predicate Device, PreXion3D Explorer EX. The enhanced detector performance represents a design improvement and does not change the intended use, diagnostic purpose, or target patient population of the device.

The higher-performance FPD of the Subject Device provides improved X-ray detection efficiency and signal-to-noise performance. As a result, diagnostically acceptable image quality can be achieved at lower X-ray exposure levels, enabling a reduction in patient radiation dose for equivalent imaging tasks. This improvement supports dose efficiency without compromising diagnostic performance.

Both devices are intended to produce two-dimensional and three-dimensional digital X-ray images of the dental, oral, maxillofacial, ENT, and neck regions and are operated in accordance with established radiation safety principles, including the ALARA principle. The Subject Device does not introduce new imaging modes, new clinical indications, or new user interactions as a result of the higher-performance detector.

Performance verification testing demonstrates that the Subject Device achieves image quality suitable for the same diagnostic applications as the Predicate Device while operating at comparable or lower radiation dose levels. Therefore, the use of a higher-performance FPD does not raise new questions of safety or effectiveness.

Accordingly, the Subject Device is substantially equivalent to the Predicate Device with respect to detector technology and radiation dose performance.

8. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of medXion NEXUS and in showing substantial equivalence to the predicate device, medXion Technologies Inc. completed a number of non-clinical performance tests. The medXion NEXUS meets all the requirements for overall design, biocompatibility, performance, and electrical safety results confirming that the design output meets the design inputs and specifications for the device.

The medXion NEXUS passed all the testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

Electrical safety and electromagnetic compatibility (EMC):

- Electrical safety testing per ABSI/AAMI ES 60601-1, IEC 60601-1-3 Ed 2.2 and IEC 60601-1-6 Ed 3.2
- Electromagnetic Safety testing per IEC 60601-1-2 Ed 4.1
- Dental extra-oral X-ray equipment testing per IEC 60601-2-63 Ed 1.2
- Acceptance testing of X-ray equipment per IEC 61223-3-4

Software Verification and Validation Testing:

- DICOM testing per NEMA PS 3.1 - 3.20
- Usability testing per IEC 62366-1:2025+A1:2020
- Software verification and validation per IEC 62304 Ed 1.1
- Software Documentation per: "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Bench Testing:

- IEC 61223-3-7:2021 for CBCT image quality and acceptance testing
- Applicable portions of IEC 60601-2-63 related to dental CBCT system performance and image quality evaluation
- Regarding the metal artifact reduction (MAR) function, we conducted verification using dummy implants and bone phantoms and confirmed that diagnostic image quality is maintained without generating new artifacts.

- Performance testing in laboratory environment was performed with PreXion3D Explorer EX (primary predicate device) of Bone Phantoms. The data was compared in order to see that the performance of the device remains substantially similar to that of the primary predicate device.

Solid State X-ray Imagers (SSXI):

- Establish the substantial equivalence of an SSXI to a previously cleared conventional radiographic SSXI per: "Guidance for the Submission of 510(k)' s for Solid State X-ray Imaging Devices"

Cyber Security:

- Cybersecurity Activities per: "Cybersecurity in Medical Devices: Quality Management System Considerations and Content of Premarket Submissions" issued on February 3, 2026

The non-clinical testing outcomes for this device are satisfactory and demonstrate similarity to those of the predicate, supporting a finding of substantial equivalence with respect to technological characteristics and performance.

9. Clinical Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

10. Cybersecurity Activities

We followed the guidance and performed the following activities:

- Cybersecurity risk assessment and threat modeling
- Software Bill of Materials (SBOM) generation and review
- Vulnerability assessment of software components and operating environment
- Evaluation of network interfaces, communication pathways, and access control mechanisms
- Review of update and patch management procedures
- Assessment of logging and monitoring capabilities
- Verification of secure configuration and deployment requirements
- Vulnerability Testing
- Penetration testing

We make post-market Cybersecurity actions as follows:

1. Collect cybersecurity information from the link described in Post-market Plan

   As of April, 2026, there is no cyber security thread and penetration by medXion's investigation.

2. Collect information if there is any cyber security breach at customer site.

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11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics that can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device(s).

The medXion NEXUS, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.