February 16, 2024

Philips Medical Systems Nederland B.V.
Gyanendra Mani Tripathi
Regulatory Approbation Officer
Veenpluis 6
5684 PC Best
The Netherlands

Re: K232420
Trade/Device Name: Zenition 30
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, OXO
Dated: August 4, 2023
Received: August 11, 2023

Dear Gyanendra Mani Tripathi:

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

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

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

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gabriela M. Rodal -S Digitally signed by Gabriela M. Rodal -S for

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232420

Device Name

Zenition 30

Indications for Use *(Describe)*

The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.

Applications:

- Orthopedic
- Neuro
- Abdominal
- Vascular
- Thoracic
- Cardiac

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K232420

510 (k) Summary

The 510(k) Summary is given in the below pages.

510(k) Summary

K232420

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

Date Prepared: August 25, 2023

Manufacturer: Philips Medical Systems Nederland B.V.
Veenpluis 6
5684 PC Best
The Netherlands
Establishment Registration Number: 3003768277

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Device:	Trade Name:	**Zenition 30**
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	90-Radiology
	Device Class:	Class II
	Primary Product Code:	OWB
	Secondary Product Code:	JAA, OXO
Primary Predicate Device:	Trade Name:	Zenition 70
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K212813
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21CFR §892.1650
	Classification Panel:	90-Radiology
	Device Class:	Class II
	Product Code:	OWB; JAA; OXO

Device description: The proposed **Zenition 30** is a mobile, diagnostic X-ray imaging and viewing system. It is designed for medical use in healthcare facilities where X-ray imaging is needed. The system comprises of two main components: the C-arm stand and a Mobile View Station (MVS).

Indications for Use: The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.
Applications:

- Orthopedic
- Neuro
- Abdominal
- Vascular
- Thoracic
- Cardiac

The proposed Philips **Zenition 30** has same indications to the currently marketed and predicate device Zenition 70 (K212813, Oct 1, 2021).

Table 1 shows that the proposed **Zenition 30** is **substantially equivalent** to the currently marketed and predicate device, *Zenition 70*, in terms of indications for use.

Table 1 Indications for use comparison of the proposed Zenition 30 versus the currently marketed and predicate device, Zenition 70

Predicate Device Zenition 70 (K212813)	**Proposed Zenition 30 (K232420)**	**Conclusion**
Indications for Use		
The Zenition 70 device is intended to be used and operated by: adequately trained, qualified and authorized health care professionals who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device. The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients, except neonates (birth to one month), within the limits of the device. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile	The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures. Applications: • Orthopedic • Neuro • Abdominal • Vascular • Thoracic • Cardiac	***Substantially Equivalent*** ***SE analysis:*** Same Both the proposed **Zenition 30** and currently marketed predicate device Zenition 70 are intended for radiological guidance and visualization during diagnostic, interventional and surgical procedures. The clinical application areas for both predicate Zenition 70 and the subject device **Zenition 30** are the same. The proposed **Zenition 30** is equipped with dedicated

environment in a variety of procedures. Applications: • Orthopedic • Neuro • Abdominal • Vascular • Thoracic • Cardiac		pediatric mode and capable of automatic dose control based on the subject size. The moment user selects the pediatric mode for acquisition, a popup message will appear on the screen to remove the grid from the flat detector to optimize the dose. The Grid is placed in such a way that it can be easily removed without use of tools. Zenition 30 has been validated on different types of phantom representing the pediatric and adult population. Therefore, **Zenition 30** demonstrates substantial equivalence with predicate Zenition 70 in terms of intended use. and do not raise questions of safety and effectiveness.

Fundamental Scientific Technology: The proposed **Zenition 30** employs the same basic construction and fundamental scientific technology as the currently marketed and predicate Zenition 70. The technology used in the development of the major components of the proposed **Zenition 30**, which includes X-ray generator, X-ray tube housing assembly, and Image detection system is similar to the currently marketed and predicate Zenition 70. Modifications implemented in the proposed **Zenition 30** include:

- State of the art flat panel detector px2020S
- New Scalable X-segment (Supports 2.1kW and 4.0kW modes)
- Introduction of the compact stand assembly
- Introducing Electro Magnetic Brakes
- Table Side UI
- Introduction of the light weight C-arc
- SCU changes
- Modification of Brake between wheels
- Introduction of general purpose I/O board(GPIO)

The risks associated with these changes were assessed and found to be acceptable. The minor differences between the **Zenition 30** and the predicate device Zenition 70 do not raise any new questions regarding safety or effectiveness. The **Zenition 30** is considered substantially equivalent to the currently marketed predicate Zenition 70 (K212813, Oct 1, 2021) in terms of fundamental scientific technology.

Table 2 shows that the proposed **Zenition 30** is considered substantially equivalent to the currently marketed predicate, *Zenition 70* in terms of major components and technological characteristics.

Table 2 Technological characteristics comparison of the currently marketed predicate device, Zenition 70 versus the proposed Zenition 30

Component /feature	**Predicate Device Zenition 70 (K212813)**	**Proposed Zenition 30 (K232420)**	**Conclusion**
X-ray Generator	-Peak output power: **15 kW** -kV range: 40-120 kV -Mode of operation: Pulse -Maximum mA: 125 mA -Pulse Rate : 30 pps (max) -iXion HF Generator -Model : 10359400	-Peak output power: **4kW** -kV Range: 40 to 110kV -Pulse/ Continuous: Pulsed and Continuous. -Maximum mA: 36mA -Pulse rate: 15 pps (max) -HF Generator -Model : IRI.37.216.001 (HF1 4.0 kW ESU)	The X-ray generator characteristics of proposed **Zenition 30** is subset of predicate Zenition 70 in terms of peak output power, kV range, mode of operation, maximum mA and pulse rate. The maximum pulse rates supported by predicate Zenition 70 and proposed **Zenition 30** are different, however, the **Zenition 30** system provides a continuous x-ray mode that works at 30 fps, this is treated as equivalent to the 30pps pulsed mode of Zenition 70. The X-ray power levels of the Zenition 70 and **Zenition 30** are different. However, the image quality of **Zenition 30** for the proposed intended use is clinically acceptable. This change does not impact the safety and effectiveness of the device. Thus, demonstrating substantial equivalence. **Conclusion:** Similar and substantially equivalent
X-ray tube	-Rotating Anode (Model: RTM 780 H (Type RO-0306) -Focal spot: dual (0.3 & 0.6) -Target angle: 10° -Anode heat content: 225kJ -Maximum anode cooling rate: 550W -Nominal anode input power: 15kW	-Fixed Anode (model: OX 125 -0612) -Focal spot: dual (0.6 & 1.2) -Target angle: 9° -Anode heat content: 57kJ -Maximum anode cooling rate: 600W -Nominal anode input power: 4kW	The target angle affects the focal spot size and field of view. As target angle of proposed **Zenition 30** and predicate Zenition-70 are similar, the field of view is also similar. Focal spot size is contributing to resolution of the image. The predicate Zenition 70 uses the 0.6 focal spot for all application modes, and in proposed **Zenition 30**, 0.6 mm focal spot is used for all the applications except for single shot at 1.2 mm focal spot for the max power demonstration.

			As both systems support a minimum limiting resolution of > =2.2 lp/mm in all detector modes, this demonstrates a similarity in the resolutions delivered to support the intended use. There is no clinically significant difference in the safety and clinical performance of **Zenition 30** as compared to predicate Zenition 70. Both the devices comply to applicable x-ray safety standards (e.g., IEC 60601-1-3, 2.1edition). **Conclusion:** Similar and substantially equivalent, technological characteristics of the devices do not raise questions of safety and effectiveness
X-ray housing assembly	iXion 5 Monoblock, model identification: 10454900 -Active oil circulation -Monoblock heat content: 1350kJ -Safety mechanisms: Thermal Switch -filtration: 1mm Al+0.1mm Cu -fluoro time: 296W for 60mins	I-40S, 3.5RF, model identification: I01.01.179.001 -Active oil circulation -Monoblock heat content: 1056kJ -Safety mechanisms: Thermal Switch -filtration: 3.8mmAl+0.1mmCu -fluoro time: 300W @ 50mins, 600W @ 20mins	The monoblock is the combination of x-ray tube, transformer and cooling oil. Having active oil circulation within the monoblock helps in heat dissipation and more available x-ray time. The proposed device **Zenition 30** has similar heat performance compared to the predicate device Zenition 70. There are no technological significant difference in the safety and clinical performance of the devices. Both the devices Zenition 70 and **Zenition 30** use the same safety mechanism of thermal switch to address undesirable overheating scenarios. Cu and Al filtration are meant to remove the low energy x-ray part of the spectrum that is not contributing to the imaging. The inherent filtration is better in **Zenition 30** compared to the predecessor device Zenition 70. **Conclusion:** Similar and substantially equivalent The proposed device **Zenition 30** is having similar heat performance as compared to the predicate Zenition 70. Both the devices share the same safety mechanism of thermal switch to

			address undesirable overheating scenarios. Additionally, the inherent filtration is better in **Zenition 30** compared to the predecessor device Zenition 70. Hence, we can conclude that both the devices share the same technological characteristics with no significant difference in the safety and effectiveness of the devices.
Flat Panel Detector	Model: 45980120023x -Frame rate: 30fps -Zoom modes: Overview mode + 2 zoom modes -Detector size (x/y): 207mm x 207mm (square) -pixel pitch: 154 µm -Image matrix: 1344x1344 -DQE: 77%	Model: PIXIUM 2020S-p -Frame rate: 30fps -Zoom modes: Overview mode + 2 zoom modes -Detector size (x/y): 204mm x 204mm (square) -pixel pitch: 200 µm -Image matrix: 1024x1024 -DQE: 80%	Both **Zenition 30** and the predicate device Zenition 70 systems use a Flat Panel (FP) digital image detector technology. The detector used in proposed device **Zenition 30** is based on the same design, scientific technology and image acquisition workflow as the Flat Panel digital image detector used in the predicate Zenition 70. The frame rates of both detectors are also the same. The physical size of the detectors are not significantly different (207 x 207 mm2 versus 204 x 204 mm2) for the predicate device Zenition 70 and the proposed device **Zenition 30**. Additionally, the number of zoom modes are also identical for both the devices. The pixel pitch of the **Zenition 30** is 200 µm, which is similar to the pixel pitch of the predicate Zenition 70 (154 µm). However, the final resolution seen at the system level is result of multiple factors. At **Zenition 30**, Zenition 70 system level, both systems demonstrate a limiting resolution > 2.2 lp/mm in all detector modes due to similar anode angle and focal spot used for the majority of the applications. DQE (detective quantum efficiency) is a measure for the x-ray dose sensitivity of the detector and defines the image quality generated from the detector. The DQE is similar for both the detectors used in predicate Zenition 70 and the proposed device **Zenition**

			30 with the sensitivity of the **Zenition 30** being slightly higher. Better sensitivity of detector used in **Zenition 30** will have an advantage over the predicate Zenition 70 in terms of image quality with same or lower X-Ray Dose. There is no change in clinically relevant characteristics of the detector used in both the devices that relate to the acquisition to X-ray images and X-ray dose sensitivity. **Conclusion:** Similar and substantially equivalent We can conclude that both the devices share the same technological characteristics with no significant difference in the safety and effectiveness of the devices
Imaging Processing technology	Xres-3	Xres-3	The predicate device Zenition 70 and the proposed device **Zenition 30** both are using the same PC-based platform, and algorithm. **Conclusion:** Same and substantially equivalent
Anti Scatter Grid	Removable grid (square) Transmission: 70%	Removable grid (square) Transmission: 70%	The proposed **Zenition 30** has a square removable grid, the same as of predicate Zenition 70. The grids are made using the same technology. **Conclusion:** Similar and substantially equivalent
Radiation safety features	Collimation Anti-scatter grid Fluoroscopy modes Pulsed fluoroscopy Recording and storing fluoroscopic runs Last image hold Real-time dose monitoring	Collimation Anti-scatter grid Fluoroscopy modes Pulsed fluoroscopy Recording and storing fluoroscopic runs Last image hold Real-time dose monitoring	The mobile x-ray c-arms have a range of features (like collimation, anti-scatter grid, different fluoroscopy modes, last image hold and real time dose monitoring) that enable the management of dose. The available features are the same on both the systems. Both the proposed device **Zenition 30** and the predicate device Zenition 70 shares the same radiation safety features. **Conclusion:** Same and substantially equivalent

Beam Limiting Device (Collimator)	Square (but round in zooming and rotation)	Square (but round in zooming and rotation)	The proposed **Zenition 30** system introduces a collimator that is reusing the collimator used in predicate device Zenition 70. One modification is made by extending the lead ring to the bottom of collimator. This is done in order to account for the minor differences in the mounting arrangement of the collimator and monoblock mounting surface. In all other aspects the collimator of predicate Zenition 70 and proposed **Zenition 30** remain the same in performance and safety parameters. Thus, demonstrating substantial equivalence. **Conclusion:** Similar and substantially equivalent
C-arm motions and brakes	4 axis movements 4 axis manual brakes	4 axis movements 3 axis electromagnetic brakes, 1 axis manual brake	The number of axis in which the c-arm movements are possible (Angulation, Rotation, Longitudinal, Wigwag) is the same for both the systems under comparison. The predicate Zenition 70 provide manual brake levers to release and lock the brakes. However, the proposed **Zenition 30** system uses electromagnetic brakes to release or lock the c-arm axis to simplify the workflow and reduce manual efforts. The electromagnetic brakes used in proposed **Zenition 30** will be an added advantage when compared with the equivalent device Zenition 70. The differences in the technology used to operate the brakes does not introduce any new risk as conformed by the usability studies and the product safety assessment carried out. **Conclusion:** Similar and substantially equivalent Both proposed **Zenition 30** and the predicate Zenition 70 has the same axis of movements and share the same technological characteristics with no significant difference in the safety and effectiveness of the devices

Geometry	Hammerhead design Size : 206 x 82 x 162 cm Weight : 332 Kg (FD12) Stand-U/I: 15.3" touch screen display	New design stand Size: 185 x 82 x 172 cm (without push bar and surgeon arm) 210 x 82 x 162 cm (with push bar and surgeon arm) Weight : 295 kg Stand-U/I: 12.1" touch screen display	In the proposed **Zenition 30**, the new stand design comes with lower C-arm operating forces, provision to mount foot switch, hand switch and other options. The design also brings in the slimmer version of the stand UI display (12.1") compared to the predicate device Zenition 70. These features will improve the workflow and help ease of use of proposed **Zenition 30** as compared to predicate Zenition 70 The new stand that is used in the proposed **Zenition 30** helps improve the maneuverability and ease of use while keeping the essence of the stand same. **Conclusion:** Similar and substantially equivalent
System architecture	PC Based Win 10	PC Based Win 10	**Conclusion:** Same and substantially equivalent
Ionizing radiation	System uses X-ray for imaging	System uses X-ray for imaging	Same X-ray technology usage **Conclusion:** Same and substantially equivalent
Detector Laser aiming device	Integrated in FD covers (Model: FP-L-635-10-34-Philips-V2-C2) Wavelength: 635 nm (±5 nm) Maximum output: 10 mW (±1 mW) Beam divergence: 34 degrees	Integrated in FD covers (Model: FP-L-635-10-34-Philips-V2-C2) Wavelength: 635 nm (±5 nm) Maximum output: 10 mW (±1 mW) Beam divergence: 34 degrees	**Conclusion:** Same and substantially equivalent
Laser Alignment tool	Tube Laser Aiming Device (Model: 4598 008 4322x)	Tube Laser Aiming Device (Model: 4598 008 4322x)	**Conclusion:** Same and substantially equivalent
DICOM connectivity	DICOM connectivity workflow -Easier selection of patient data for export -Introduced unattended network transfer of export jobs	DICOM connectivity workflow -Easier selection of patient data for export -Introduced unattended network transfer of export jobs	**Conclusion:** Same and substantially equivalent

	-Integrated workflow for export to local media (USB and DICOM DVD) -Improved workflow for multimodality viewer functionality -Improved DICOM transfer speed	-Integrated workflow for export to local media (USB and DICOM DVD) -Improved workflow for multimodality viewer functionality -Improved DICOM transfer speed	
Security features	-Local user account management -Function improved to enable a username/password combination. -Network time synchronization -Different implementation only -Audit trail -White listing -DIACAP hardening -Disk encryption -FIPS 140-2	-Local user account management -Function improved to enable a username/password combination. -Network time synchronization -Different implementation only -Audit trail -White listing -DIACAP hardening -Disk encryption -FIPS 140-2	**Conclusion:** Same and substantially equivalent.
Room Interface	External x-ray and power indication interface	External x-ray and power indication interface	**Conclusion:** Same and substantially equivalent.
Audible signals	Speaker with volume control added in the Stand	Speaker with volume control added in the Stand	**Conclusion:** Same and substantially equivalent.
Wired Footswitch and remote control unit	Same	Same	**Conclusion:** Same and substantially equivalent.
Product Name	Zenition 70	New Product name **Zenition 30**	Labeling change that has no impact on system features, safety and effectiveness. Thus, demonstrating substantial equivalence

Summary of Non-Clinical Performance Data:

Non-clinical performance testing has been performed on the proposed **Zenition 30** and demonstrates compliance with the following International and FDA-recognized consensus standards and FDA guidance documents.

- IEC 62304 Medical device software – Software life cycle processes (Edition 1.1, 2015). FDA/CDRH recognition number 13-79.
- ISO 14971 Medical devices – Application of risk management to medical devices (Edition 2.0, corrected version, 2019). FDA/CDRH recognition number 5-125.
- IEC 60601-2-43 - Particular requirements for the safety of X-Ray equipment for interventional procedures (Edition 2.2, 2019). FDA/CDRH recognition number 12-329.
- IEC 60601-2-54, Medical Electrical Equipment- Part 2-54: Particular Requirements for the Basic Safety and Essential Performance of X-Ray Equipment for Radiography and Radioscopy (Edition 1.2 2018). FDA/CDRH recognition number 12-317.
- IEC 60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance (Edition 3.1). FDA/CDRH recognition number 19-4.
- IEC 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility – Requirements and tests (Edition 4.1 2020). FDA/CDRH recognition number 19-36.
- IEC 60601-1-3, Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance.-Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment. (Edition 2.1 2013). FDA/CDRH recognition number 12-269.
- IEC 60601-1-6, Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Usability (Edition 3.1 2013). FDA/CDRH recognition number 5-89.
- IEC 62366-1 IEC Application of Usability Engineering to Medical Devices (Edition 1.1 2020). FDA/CDRH recognition number 5-129
- ISO 15223-1, Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied (Edition 4.0 2021). FDA/CDRH recognition number: 5-134.
- ISO 20417 Medical devices - Information to be supplied by the manufacturer (First edition 2021-04 Corrected version 2021-12). FDA/CDRH recognition number 5-135
- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices (issue date: 01-Sep-2016)
- Pediatric Information for X-ray Imaging Device Premarket Notifications (Issue Date: 28-Nov-2017)
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (11-May-2005)
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (02-Oct-2014)
- Guidance for Industry and FDA Staff - Applying Human Factors and Usability Engineering to Medical Devices(document number (03-Feb-2016)
- Radio frequency wireless technology in medical devices- Guidance for Industry and Food and Drug Administration Staff (14-Aug-2013)

Non-clinical validation testing has been performed to cover the intended use, commercial claims, service, user needs, effectiveness of safety measures, instructions for use, and usability testing with representative intended users.

Non-clinical verification and validation demonstrate that the **Zenition 30**:

- Complies with the aforementioned international and FDA recognized consensus standards and FDA guidance documents.
- Meets the acceptance criteria and is adequate for its intended use.

Therefore, the **Zenition 30** is substantially equivalent to the currently marketed and predicate Zenition 70 (K212813, Oct 1, 2021) in terms of safety and effectiveness.

Summary of Clinical Performance Data:

The 11-inch detector in **Zenition 30** has similar design, technology and Image acquisition workflow compared to the previously cleared detector used in the marketed predicate device Zenition 70. All technical detector characteristics that potentially have an influence on image quality are assessed and verified according to FDA Guidance for Industry and Food and Drug Administration Staff: Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices. So, no clinical information was used to support the substantial equivalence as per FDA Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices.

Substantial Equivalence Conclusion:

The **Zenition 30** is substantial equivalent to the currently marketed predicate device *Zenition 70* (K212813, Oct 1, 2021) in terms of indications for use, fundamental scientific technology and safety and effectiveness.

Additionally, substantial equivalence was demonstrated by non-clinical performance tests. These tests demonstrate that **Zenition 30** complies with the requirements specified in the international and FDA-recognized consensus standards and guidance and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.