August 7, 2026

Philips Medical Systems Nederland B.V.
% Gyanendra Mani Tripathi
Senior RA Business Specialist
Veenpluis 6
BEST, 5684PC
NETHERLANDS

Re: K254205
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: July 8, 2026
Received: July 9, 2026

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 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,

FDA Digitally signed by GABRIELA M. RODAL -S for

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K254205

Please provide the device trade name(s).

Zenition 30

Please provide your Indications for Use below.

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

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

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

510(k) Summary

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

Date Prepared:	December 24, 2025	
Manufacturer:	Philips Medical Systems Nederland B.V. Veenpluis 6 5684 PC Best The Netherlands Establishment Registration Number: 3003768277	
Primary Contact Person:	Gyanendra Mani Tripathi Senior RA Business Specialist Phone: +91 9873846827 E-mail: gyanendramani.tripathi@philips.com	
Secondary Contact Person:	Sumit Kumar Head of Regulatory Affairs Phone: +91 7028039288 E-mail: sumit.kumar_3@philips.com	
Device:	Trade Name:	**Zenition 30**
	Classification Name:	Image-intensified fluoroscopic x-ray system
	Classification Regulation:	21 CFR §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 30
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K232420
	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
Reference Device	Trade Name:	Zenition 70
	Manufacturer:	Philips Medical Systems Nederland B.V.
	510(k) Clearance:	K183040
	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 **Zenition 30** has identical indications for use as of the currently marketed and predicate Zenition 30 (K232420, Feb 16, 2024). Based on the information provided above, the proposed **Zenition 30** is considered substantially equivalent to the currently marketed and predicate device Zenition 30 (K232420, Feb 16, 2024) in terms of **Indications for Use.**

Fundamental Scientific Technology:

The proposed **Zenition 30** employs the same basic construction and fundamental scientific technology as the currently marketed predicate device Zenition 30 (K232420, Feb 16, 2024). The technology used in the development of the major components of the modified proposed **Zenition 30**, which includes X-ray generator, X-ray tube housing assembly, and Image detection system is identical to the currently marketed Zenition 30 (K232420, Feb 16, 2024). Modifications implemented in the modified proposed **Zenition 30** include:

1) **Addition of alternate X-ray tube in the X-ray Tube Housing Assembly (Monobock):**
   The predicate Zenition 30 device (K232420, February 16, 2024) currently contains X-Ray tube (model: OX/125-0612) manufactured by CEI S.R.L. in the X-ray Tube Housing Assembly (Monoblock) manufactured by IMD Generators SRL.
   The X-ray Tube Housing Assembly (Monoblock) serves as X-Ray source to the X-Ray Machine.

The proposed change involves introducing an **alternative X-ray tube (model: KL188-0.6/1.2-125),** manufactured by "Hangzhou Kailong Medical Instruments Co. Ltd." in addition to the existing X-ray tube (model: OX/125-0612), manufactured by CEI S.R.L in the X-ray Tube Housing Assembly (Monoblock) manufactured by IMD Generators SRL.

It is important to note that Philips Medical Systems Nederland B.V., does not procure X-ray tubes separately. Instead, Philips Medical Systems Nederland B.V purchases finished Tube Housing Assembly (Monoblock) from IMD Generators SRL (the manufacturer), where the X-ray tube is an integrated component.

The proposed **Zenition 30** will have two configurations of Tube Housing Assembly (Monoblock):
-Tube Housing Assembly (Monoblock) with the X-Ray tube (model: OX/125-0612) manufactured by CEI S.R.L or
-Tube Housing Assembly (Monoblock) with the X-Ray tube (model: KL188-0.6/1.2-125) manufactured by Hangzhou Kailong Medical Instruments Co. Ltd.

The technical data specifications of the X-ray Tube Housing Assembly (Monoblock) remain the same. **Table 1** of the section concludes technical data equivalence.

However, as mentioned earlier, the X-ray Tube Housing Assembly (Monoblock) (incorporating the X-ray tube in it) design itself remains unchanged. Additionally, the X-ray Tube Housing Assembly (Monoblock) and the proposed **Zenition 30** device maintain the same specifications as earlier (continue to meet the original specifications without any deviation). The product risk assessment confirms that the system's risk profile remains unaffected, with no impact on the intended use.

Along with this primary change there are other minor related changes, as listed below:
Inverter firmware updates - to improve quick reset behavior;
Software updates - to add the IDs of the X-ray Tube Housing Assembly (Monoblock) with X-ray tube manufactured by Hangzhou Kailong Medical Instruments Co. Ltd. Configuration;
Stand UI Software version changes from 5.0.1 to 5.0.2 – to correct the startup copyright message for Zenition 30.

2) Addition of optional Wireless Footswitch

The Philips Medical Systems Nederland B.V., Zenition 30 (K232420, February 16, 2024), currently contains a hand switch (integral part of the device) and a Wired Footswitch (option) which serves as an additional control switch. With this 510(k) submission, Philips intends to introduce Wireless Footswitch as an additional option in proposed **Zenition 30** Device. The user will have flexibility to choose the options as per need. Wireless footswitch serves the same intended purpose as Hand switch (integral part of the device) and wired footswitch (option).

This is to emphasize that in addition to the foot switches (wired and wireless), there is an additional hand switch (integral part of the Device) which is used to control the exposure of X-Ray from the proposed device **Zenition 30**.

The proposed wireless footswitch is equivalent to the currently marketed wired footswitch and provides the same functions as the wired foot switch.

The wireless footswitch integrated is the updated wireless footswitch design cleared under K251827. With this 510(k) submission, the same US FDA cleared wireless footswitch is intended to be added as an additional option to the proposed device **Zenition 30**.

The risks associated with these changes were assessed and found to be acceptable. The minor differences between the modified proposed **Zenition 30** and the marketed device Zenition 30 (K232420, Feb 16, 2024) do not raise any new questions regarding safety or effectiveness. The proposed **Zenition 30** is considered substantially equivalent to the currently marketed predicate Zenition 30 (K232420, Feb 16, 2024) in terms of fundamental scientific technology.

Table 1 below shows that the modified proposed **Zenition 30** is considered substantially equivalent to the currently marketed predicate Zenition 30 (K232420, Feb 16, 2024) in terms of major components and technological characteristics.

Table 1 Technological characteristics comparison of the currently marketed predicate device, Zenition 30 (K232420, February 16, 2024) versus the proposed Zenition 30

Component /feature	**Marketed Device Zenition 30** (K232420, February 16, 2024),	**Proposed Zenition 30**	**Conclusion**
X-Ray Generator	-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)	-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)	All the parameters of X-Ray Generator of proposed Device **Zenition 30** are Identical to the X-Ray Generator of predicate device Zenition 30 (K232420, February 16, 2024). ***Substantial Equivalence analysis**:* Identical to predicate device and Substantially Equivalent

X-Ray Tube	**-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	**-Fixed Anode (model: KL188-0.6/1.2-125)** -Focal spot: dual (0.6 & 1.2) -Target angle: 10° -Anode heat content: 53kJ -Maximum anode cooling rate: 600W -Nominal anode input power: 5kW	The monobloc (X-ray tube housing assembly) construction remains the same for the both tubes. Focal spot is same. The minor differences in the target angle don't impact the minimum limiting resolution of > =2.2 lp/mm in all detector modes. This table demonstrates that both the CEI OX/125-0612 and Kailong KL188-0.6/1.2-125 X-Ray tubes are functionally equivalent for use in the IMD monoblock, with minor differences in maximum heat capacity. At maximum heating, the anode cools down to lowest heat content in 20 minutes. All safety and operational limits are managed by the system software according to the respective thermal models with a consistent workflow. ***Substantial Equivalence analysis**:* Similar and Substantially Equivalent, the slight difference in technological

			characteristics of the new X-Ray Tube model (model: KL188-0.6/1.2-125) will not raise any questions of safety and effectiveness of proposed device **Zenition 30**.
X-ray tube housing assembly	Active oil circulation Monoblock heat content: 1056kJ Safety mechanisms: Thermal Switch filtration: 3.8mmAl+0.1mmCu Fluoro time: 300W @ 50mins, 600W @ 20mins.	Active oil circulation Monoblock heat content: 1056kJ Safety mechanisms: Thermal Switch filtration: 3.8mmAl+0.1mmCu Fluoro time: 300W @ 50mins, 600W @ 20mins.	***Substantial Equivalence analysis**:* Identical to predicate device and Substantially Equivalent
Detectors (Image detection subsystem)	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%	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%	***Substantial Equivalence analysis**:* Identical to predicate device and Substantially Equivalent
Detachable Grids	FD11 – Removable grid square Transmission: 67%	FD11 – Removable grid square Transmission: 67%	***Substantial Equivalence analysis**:* Identical to predicate device and Substantially Equivalent
Collimator (Beam limiting device)	Square (but round in zooming and rotation) Automatic shutter positioning 2 Independent Shutters.	Square (but round in zooming and rotation) Automatic shutter positioning 2 Independent Shutters.	***Substantial Equivalence analysis**:* Identical to predicate device and Substantially Equivalent
Detector laser aiming device	Integrated in FD covers (Model: FP-L-635-10-34-Philips-V2-C2)	Integrated in FD covers (Model: FP-L-635-10-34-Philips-V2-C2)	***Substantial Equivalence analysis**:*

	Wavelength: 635 nm (±5 nm) Maximum output: 10 mW (±1 mW) Beam divergence: 34 degrees	Wavelength: 635 nm (±5 nm) Maximum output: 10 mW (±1 mW) Beam divergence: 34 degrees	Identical to predicate device and Substantially Equivalent
Mobile C- arm Stand	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	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	***Substantial Equivalence analysis**:* Identical to predicate device and Substantially Equivalent
Mobile Viewing Station	Live and Reference monitor for visualization Patient Administration New color scheme	Live and Reference monitor for visualization Patient Administration New color scheme	***Substantial Equivalence analysis**:* Identical to predicate device and Substantially Equivalent.
DICOM connectivity	DICOM connectivity workflow -Easier selection of patient data for export -Introduced unattended network transfer of export jobs -Integrated workflow for export to local media (USB and DICOM DVD) -Improved workflow for multimodality viewer functionality -Improved DICOM transfer speed	DICOM connectivity workflow -Easier selection of patient data for export -Introduced unattended network transfer of export jobs -Integrated workflow for export to local media (USB and DICOM DVD) -Improved workflow for multimodality viewer functionality -Improved DICOM transfer speed	***Substantial Equivalence analysis**:* Identical to predicate device and Substantially Equivalent
Operating System	Windows 10 LTSC 2019	Windows 10 LTSC 2019	***Substantial Equivalence analysis**:* Identical to predicate device and Substantially Equivalent.

Irradiation Switch	- Handswitch - Wired Footswitch (option)	- Handswitch - Wired Footswitch (option) - Wireless footswitch (option)	The currently marketed predicate device Zenition 30 (K232420, February 16, 2024), is equipped with hand switch and optional wired foot switch. The proposed **Zenition 30** has additional option of wireless foot switch which is functionally same as a wired foot switch. Additionally, the Handswitch is integral part of the proposed Device **Zenition 30** as well as Zenition 30 (K232420, February 16, 2024) as an additional control (Irradiation Switch). The wireless footswitch helps avoid cable clutter on the floor. The proposed **Zenition 30** with wireless foot switch complies with all prevailing safety standards IEC 60601-1 ed 3.2, radiation safety standard IEC 60601-2-43 ed 3 , IEC 60601-2-54 ed 2 and also its collateral standard that supports safety by ensuring electromagnetic compatibility and essential performance of medical electrical equipment. IEC60601-1-2 ed 4.1.

			The same wireless footswitch is already FDA cleared under K251827. There are no clinically significant differences in the safety, effectiveness and clinical performance of the proposed **Zenition 30** as compared to predicate device Zenition 30 (K232420, February 16, 2024). ***Substantial Equivalence analysis****:* Similar and Substantially Equivalent
Imaging Processing technology	Xres-3 PC-based platform, and algorithm.	Xres-3 PC-based platform, and algorithm.	***Substantial Equivalence analysis****:* Identical and Substantially Equivalent

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 CONSOLIDATED VERSION -Medical device software – Software life cycle processes (Edition 1.1, 2015-06). FDA/CDRH recognition number 13-79. • ISO 14971 Medical devices – Application of risk management to medical devices (Edition 3.0, 2019-12). FDA/CDRH recognition number 5-125. • IEC 60601-2-43 - Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures (Edition 3.0, 2022-12). FDA/CDRH recognition number 12-351. • 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 2.0, 2022-09). FDA/CDRH recognition number 12-348 • ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]. FDA/CDRH recognition number 19-46. • IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (Edition 4.1, 2020-09). FDA/CDRH recognition number 19-36. • IEC 60601-1-3 CONSOLIDATED VERSION, Medical Electrical Equipment Part 1-3: General Requirements for Basic Safety and Essential Performance.-Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment. (Edition 2.2, 2021-01. FDA/CDRH recognition number 12-336. • IEC 60601-1-6 CONSOLIDATED VERSION, Medical Electrical Equipment Part 1-6: General Requirements for Basic Safety and Essential Performance- Collateral Standard: Usability (Edition 3.2 2020-07. FDA/CDRH recognition number 5-132. • IEC 62366-1 IEC Application of Usability Engineering to Medical Devices (Edition 1.1, 2020-06). 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, 2021-07). 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, document number 644) • Pediatric Information for X-ray Imaging Device Premarket Notifications (Issue Date: 28-Nov-2017, document number 1771) • Content of Premarket Submissions for Device Software Functions, 14- June-2023 (document number GU100000337) • Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (27-Jun-2025, document number GUI00001825)

	• Guidance for Industry and FDA Staff - Applying Human Factors and Usability Engineering to Medical Devices (03-Feb-2016, document number 1757) • Radio frequency wireless technology in medical devices- Guidance for Industry and Food and Drug Administration Staff (14-Aug-2013, document number 1618) Non-clinical validation testing and sample clinical image evaluation has been performed to cover the modifications proposed in the Zenition 30 Device. Non-clinical verification and validation and clinical image evaluationdemonstrate that the proposed **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 proposed **Zenition 30** is substantially equivalent to the currently marketed and predicate Zenition 30 (K232420, Feb 14, 2024) in terms of safety and effectiveness.
Summary of Clinical Performance Data:	The proposed **Zenition 30** did not require clinical study since substantial equivalence to the currently marketed and predicate device Zenition 30 (K232420, Feb 14, 2024) was demonstrated with the following attributes: • Indications for use; • Technological characteristics; • Non-clinical performance testing; and • Safety and effectiveness. Furthermore, the alternate X-Ray Tube Housing Assembly (Monoblock) (containing the X-Ray tube manufactured by Hangzhou Kailong Medical Instruments Co. Ltd.) used in proposed device **Zenition 30**, has similar design, technology and specifications compared to the existing X-Ray Tube Housing Assembly (containing X-Ray tube manufactured by CEI S.R.L) used in the predicate device Zenition 30 (K232420, Feb 14, 2024). Both variants of X-ray Tube Housing Assemblies (Monoblocks) are manufactured by the same manufacturer (IMD Generators SRL). The optional wireless footswitch introduced in the proposed **Zenition 30** has the same purpose of activation of X-Ray source as of already available hand switch (integral part of the device) and optional wired footswitch. Additionally**,** the similar wireless footswitch which is already cleared by FDA under K251827 and marketed in the US with proven safety, effectiveness, performance characteristics and utilizes similar design and technology.

Substantial Equivalence Conclusion:	The proposed **Zenition 30** is substantially equivalent to the currently marketed predicate device Zenition 30 (K232420, Feb 14, 2024) in terms of indications for use, fundamental scientific technology, safety and effectiveness. The modification of the proposed **Zenition 30** is within the controls and predetermined specifications. Additionally, substantial equivalence was demonstrated by non-clinical performance tests. These tests demonstrate that proposed **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.