February 14, 2024

Philips Medical Systems DMC GmbH
℅ Shalin Dave
Head of Regulatory Affairs DXR
Röntgenstraße 24
Hamburg, 22335
GERMANY

Re: K233678
Trade/Device Name: Radiography 7000 M
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: November 8, 2023
Received: November 16, 2023

Dear Shalin Dave:

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,

Lu Jiang

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

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)*
K233678

Device Name

Radiography 7000 M

Indications for Use *(Describe)*

The Radiography 7000 M is intended for diagnostic procedures on both adult and pediatric patients who are unable to be transferred to the stationary X-ray system. It enables radiographic imaging of various body parts, including the skull, chest, spine, shoulders, pelvis, extremities, abdomen, and other body regions. The system allows for applications in different positions, such as sitting, standing, and lying in either a prone or supine position. However, it should be noted that the system is not suitable for mammography applications.

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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510(k) Summary of Safety and Effectiveness

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

Preparation Date:	November 14th , 2023
510(k) Owner:	Philips Medical Systems DMC GmbH Röntgenstrasse 24 22335 Hamburg GERMANY Establishment registration number: 3003768251
Primary Contact:	Shalin Dave Head of Regulatory Affairs DXR Phone: +31 (6) 4253260 E-mail: shalin.dave@philips.com
Secondary Contact:	Ming Xiao Regulatory Affairs Manager Phone: +49(40) 34971-2306 E-mail: ming.xiao@philips.com

Proposed Device

Device Name	Radiography 7000 M
Legal Manufacturer	Philips Medical Systems DMC GmbH Röntgenstrasse 24 22335 Hamburg GERMANY
Classification Name:	Mobile x-ray system
Classification Regulation:	892.1720
Classification Panel:	90 – Radiology
Device Class:	Class II
Product Code:	IZL

Predicate Device

Device Name	MobileDiagnost wDR 2.2
Legal Manufacturer	Philips Medical Systems DMC GmbH Röntgenstrasse 24 22335 Hamburg GERMANY
Classification Name:	Mobile x-ray system
Classification Regulation:	892.1720
Classification Panel:	90 – Radiology
Device Class:	Class II
Product Code:	IZL, MQB

Reference Device # 1

Device Name	SM-IV
Legal Manufacturer	SEDECAL SA

	C/ Pelaya, 9 – 13, Pol. Ind. Río de Janeiro22335 Hamburg 28110 Algete, Madrid España (Spain) Tel.- +34 91 6280544 Fax.- +34 91 6280574
Classification Name:	Mobile x-ray system
Classification Regulation:	892.1720
Classification Panel:	90 – Radiology
Device Class:	Class II
Product Code:	IZL

Device Description:
The Radiography 7000 M digital mobile will be a new motorized mobile x-ray system that will employ integrated wireless flat panel detectors of two different sizes (large and small) to obtain digital images in mobile environments; the system will also be able to utilize CR or traditional film cassettes in a back-up scenario. The system will primarily use wireless technology for image acquisition and the transmission of images to archive systems like PACS, as well as for the retrieval of patient and exam information from the radiology information system (RIS) or hospital information system (HIS).
The system is available in the following configurations.
• with 20 kW X-ray generator
• with 40 kW X-ray generator

The Radiography 7000 M system is an integrated system consisting of the following subsystems:
• Base Unit (Sedecal Mobile X-ray system - SM-IV, cleared under K232185 August 21, 2023)
• SkyPlate Family of detectors (Wireless Portable Detectors) and their accessories
• Eleva WorkSpot 43.0

The "Radiography 7000M" complies with the requirements specified in FDA's device specific guidance document entitled, "Guidance for the submission of 510(k) for solid state X-ray Imaging Device – September 1, 2016." Compliance with Sections I through VI, VIII and IX, which includes Table of contents, Scope, Purpose, Description, Regulatory Requirements, Non-Clinical Considerations, Labeling and Quality Assurance Program, of the FDA guidance document for the detectors is demonstrated in this submission.

Indications for Use:
The Radiography 7000 M is intended for diagnostic procedures on both adult and pediatric patients who are unable to be transferred to the stationary X-ray system. It enables radiographic imaging of various body parts, including the skull, chest, spine, shoulders, pelvis, extremities, abdomen, and other body regions. The system allows for applications in different positions, such as sitting, standing, and lying in either a prone or supine position. However, it should be noted that the system is not suitable for mammography applications.

Fundamental Scientific Technology
The proposed Radiography 7000 M is substantially equivalent to the manufacturer's legally marketed devices:

- Predicate Device: MobileDiagnost wDR 2.2 (K191813 - August 2, 2019), Philips Medical Systems DMC

A detailed comparison of the proposed and predicate device (K191813) is provided in Table 1.

Table 1: Comparison of the design feature of the currently marketed and predicate MobileDiagnost wDR 2.2 versus the proposed Radiography 7000 M			
	Predicate Device: MobileDiagnost wDR 2.2 (K191813, SE date on August 2, 2019)	***Proposed Device: Radiography 7000 M (K233678)***	***Discussion & Conclusion***
Clinical characteristics			
Intended use	The MobileDiagnost wDR is suitable for all routine radiographic exams, including specialty areas such as intensive care, trauma, operating room, or pediatric work. Standard radiography procedures are, for example: - X-ray examinations of the skeleton including skull, chest, spine, pelvis, upper extremities, lower extremities, etc. - X-ray examinations of the lung - X-ray examinations of soft tissue such as abdomen	The Radiography 7000 M is intended for diagnostic procedures on both adult and pediatric patients who are unable to be transferred to the stationary X-ray system. It enables radiographic imaging of various body parts, including the skull, chest, spine, shoulders, pelvis, extremities, abdomen, and other body regions. The system allows for applications in different positions, such as sitting, standing, and lying in either a prone or supine position. However, it should be noted that the system is not suitable for mammography applications.	No difference in characteristics between products. Conclusion: Same
Site of the body	Whole Body	Whole Body	No difference in characteristics between products. Conclusion: Same
Population	Any type of patient	Any type of patient	No difference in characteristics between products. Conclusion: Same
Basic Information			

Table 1: Comparison of the design feature of the currently marketed and predicate MobileDiagnost wDR 2.2 versus the proposed Radiography 7000 M			
	Predicate Device: MobileDiagnost wDR 2.2 (K191813, SE date on August 2, 2019)	***Proposed Device: Radiography 7000 M (K233678)***	***Discussion & Conclusion***
Design			This difference does not impact the safety or effectiveness of the device; Hence demonstrating Substantial Equivalence.
Configuration	Battery Operated Mobile	Battery Operated Mobile	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Battery	Lead Acid	lithium-ion (Li-ion) with advanced battery management system	Li-Ion battery-based solution brings smart battery management/monitoring system with fast charging. No impact on clinical needs and safety of the device; Hence demonstrating substantial equivalence.
Weight	580kg	450 kg (992 lb)	This difference does not impact the safety or effectiveness of the device; Hence demonstrating Substantial Equivalence.
Dimensions: (l x w x h) In operation max.	2577 mm x 670 mm x 2125 mm	2670 mm x 540 mm x 2220 mm	The differences in the dimensions do not impact the safety or effectiveness of the device. Hence demonstrating Substantial Equivalence.
Dimensions: (l x w x h) In transport	1382 mm x 670 mm x 1960 mm	1340 mm x 540 mm x 1285 mm	The differences in the dimensions do not impact the safety or effectiveness of the device. Hence demonstrating Substantial Equivalence.

Table 1: Comparison of the design feature of the currently marketed and predicate MobileDiagnost wDR 2.2 versus the proposed Radiography 7000 M			
	Predicate Device: MobileDiagnost wDR 2.2 (K191813, SE date on August 2, 2019)	***Proposed Device: Radiography 7000 M (K233678)***	***Discussion & Conclusion***
Dimensions: Source - floor distance	530 mm to 2020 mm	530 mm to 2020 mm	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Tube Head Display	Not Available	Available with touch screen – 8.4”	This difference does not impact the safety or effectiveness of the device; Hence demonstrating Substantial Equivalence.
Head-assembly movements	Friction based movements	Electromagnetic brakes for omnidirectional Head assembly movement handle with capacitive touch technology based	This difference does not impact the safety or effectiveness of the device; Hence demonstrating Substantial Equivalence.
Monitor (Main Screen)	Non DICOM Touch (single) screen – 17”	DICOM Multi-touch main screen – 21.5”	This difference does not impact the safety or effectiveness of the device; Hence demonstrating Substantial Equivalence.
Status Light Indicator	NA (Not Available)	Status Light Indicator on column assembly to indicate system ready for exposure	This difference does not impact the safety or effectiveness of the device; Hence demonstrating Substantial Equivalence.
Smart Power ON / Login	keypad based	Smart on/off using RFID	This difference does not impact the safety or effectiveness of the device; Hence demonstrating Substantial Equivalence.
X ray Tube assembly rotation around telescope arm axis	+/-180°	±180°	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.

Table 1: Comparison of the design feature of the currently marketed and predicate MobileDiagnost wDR 2.2 versus the proposed Radiography 7000 M			
	Predicate Device: MobileDiagnost wDR 2.2 (K191813, SE date on August 2, 2019)	***Proposed Device: Radiography 7000 M (K233678)***	***Discussion & Conclusion***
X ray tube assembly around longitudinal tube axis	+90° to -30°	110° 120° (+90° to -30°)	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Mains Supply	100 VAC/110 VAC/230 VAC±10% 50 Hz/60 Hz	100 – 240V (+/- 10% included in the range) 50 Hz/60 Hz	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Mode of Releasing Exposure	Releasing Exposure via Hand switch or via Remote Control (Optional)	Releasing Exposure via Hand switch or via Remote Control (Optional)	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Available Exposure Methods	Free exposure technique on film cassettes or CR systems and wireless portable detectors	Free exposure technique on film cassettes or CR systems and wireless portable detectors	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Dead-man handle	Dead-man handle based on micro switch mechanism	Dead-man handle with Capacitive touch technology	This difference does not impact the safety or effectiveness of the device; Hence demonstrating Substantial Equivalence.
Collision detection	From front	From front and partially from side	This difference does not impact the safety or effectiveness of the device; Hence demonstrating Substantial Equivalence.
Detector			
Type	Digital wireless flat detector	Digital wireless flat detector	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.

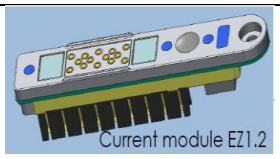
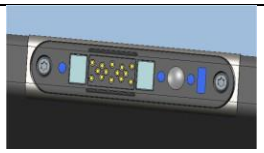
Table 1: Comparison of the design feature of the currently marketed and predicate MobileDiagnost wDR 2.2 versus the proposed Radiography 7000 M			
	Predicate Device: MobileDiagnost wDR 2.2 (K191813, SE date on August 2, 2019)	***Proposed Device: Radiography 7000 M (K233678)***	***Discussion & Conclusion***
Detector Models	SkyPlate Large (Trixell 3543EZ 1.2) Skyplate Small (Trixell 2430EZ 1.2) SkyPlate E large (Trixell 3543DR)	SkyPlate Large (Trixell 3543EZ 1.3) Skyplate Small (Trixell 2430EZ 1.3) SkyPlate E large (Trixell 3543DR)	The difference in the subject device is additional protection provided for liquid and dust ingression. This difference does not impact the safety or effectiveness of the device. Hence demonstrating Substantial Equivalence.
Detector Size	Large: 384 x 460 x 15 mm Small: 328 x 268 x 15 mm SkyPlate E Large: 384.5 x 460.5 x 15 mm	Large: 386 x 460 x 16 mm Small: 328 x 269 x 16 mm SkyPlate E Large: 384 x 460.5 x 15 mm	Length and width of the plastic body increased to support bigger sealing layers This difference does not impact the safety or effectiveness of the device. Hence demonstrating Substantial Equivalence.
On/off connector unit			Side view (Cut), improved sealing: - Additional screw hole on the opposite side for homogenious fixation over the whole area - Bigger screw head type to better cover the holes. - New fixation screws are self-locking. This difference does not impact the safety or effectiveness of the device. Hence demonstrating Substantial Equivalence.
X-Ray Absorber	CsI Scintillator	CsI Scintillator	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.

Table 1: Comparison of the design feature of the currently marketed and predicate MobileDiagnost wDR 2.2 versus the proposed Radiography 7000 M			
	Predicate Device: MobileDiagnost wDR 2.2 (K191813, SE date on August 2, 2019)	***Proposed Device: Radiography 7000 M (K233678)***	***Discussion & Conclusion***
Installation type	Portable	Portable	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Readout Mechanism	Thin Film Transistor	Thin Film Transistor	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Maximum X- ray Dose for Linear Response	50 µGy	50 µGy	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Maximum Usable Dose	75 µGy	75 µGy	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Image Processing	Eleva Workstation	Eleva Workspot	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Maximum Lifetime Dose	100 µGy	100 µGy	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Detector Weight	Max 3.1 kg including battery	Max 3.1 kg including battery	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.

Table 1: Comparison of the design feature of the currently marketed and predicate MobileDiagnost wDR 2.2 versus the proposed Radiography 7000 M			
	Predicate Device: MobileDiagnost wDR 2.2 (K191813, SE date on August 2, 2019)	***Proposed Device: Radiography 7000 M (K233678)***	***Discussion & Conclusion***
Image Size (X-ray field)	345.0 mm x 426.0 mm	345.0 mm x 426.0 mm	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Pixel Size	160 µm	160 µm	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Image matrix size (Number of pixels)	2156 x 2653 pixels	2156 x 2653 pixels	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Nyquist Frequency	3.38 lp/mm 3.125 lp/mm	3.38 lp/mm 3.125 lp/mm	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Modulation Transfer Function (MTF), typical values	**SkyPlate (543EZ & 2430EZ)** 0.5 lp/mm 81% 1 lp/mm 63% 1.5 lp/mm 47% 2.0 lp/mm 35% 2.5 lp/m 26% 3.0 lp/mm 19% (Nyquist) **SkyPlate E (3543DR)** 0.5 lp/mm 80% 1 lp/mm 62% 1.5 lp/mm 47% 2.0 lp/mm 34% 2.5 lp/m 25% 3.0 lp/mm 18% (Nyquist)	**SkyPlate (543EZ & 2430EZ)** 0.5 lp/mm 81% 1 lp/mm 63% 1.5 lp/mm 47% 2.0 lp/mm 35% 2.5 lp/m 26% 3.0 lp/mm 19% (Nyquist) **SkyPlate E (3543DR)** 0.5 lp/mm 80% 1 lp/mm 62% 1.5 lp/mm 47% 2.0 lp/mm 34% 2.5 lp/m 25% 3.0 lp/mm 18% (Nyquist)	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.

Table 1: Comparison of the design feature of the currently marketed and predicate MobileDiagnost wDR 2.2 versus the proposed Radiography 7000 M			
	Predicate Device: MobileDiagnost wDR 2.2 (K191813, SE date on August 2, 2019)	***Proposed Device: Radiography 7000 M (K233678)***	***Discussion & Conclusion***
Detective Quantum Efficiency (DQE), typical values	DQE at 2.0 µGy Lp/mm % 0.05 70 1 51 2 42 3 22 3.125 18 (Nyquist)	DQE at 2.0 µGy Lp/mm % 0.05 70 1 51 2 42 3 22(Nyquist)	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
ADC Digitization	16 Bit	16 Bit	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Signal to Electronic Noise Ratio (SENR)	Min 37 dB - typical: 42.8 dB (@ 1 µGy)	Min 38 dB - typical: 44 dB (@ 1 µGy) Min 37 dB - typical: 42.8 dB (@ 1 µGy)	Similar; No impact to safety or effectiveness of the device; Hence demonstrating Substantial Equivalence
Data Interface to Workstation	AP to workspot: 1 GBit/s Ethernet Detector Ethernet via BUC: 100 Mbit/s Ethernet Detector to AP: 150 Mbit/s WLAN (gross transfer rate)	AP to workspot: 1 GBit/s Ethernet Detector Ethernet via BUC: 100 Mbit/s Ethernet Detector to AP via WLAN (Aruba 303 WAP): 5GHz – 867 Mbps 2.4GHz – 300 Mbps	This difference does not impact the safety or effectiveness of the device. Hence demonstrating Substantial Equivalence.
Grids			
Type	Large Grids for SkyPlate Large (468 mm x 476 mm x 25mm) Small Grid for SkyPlate Small mm x 354 mm x 25 mm) Large Grids for SkyPlate E (468 mm x 476 mm x 23 mm)	Large Grids for SkyPlate Large (468 mm x 476 mm x 25 mm) Small Grid for SkyPlate Small (280 mm x 354 mm x 25 mm) Large Grids for SkyPlate E (468 mm x 476 mmx 25 mm)	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Design characteristics			
X - Ray Tube			

Table 1: Comparison of the design feature of the currently marketed and predicate MobileDiagnost wDR 2.2 versus the proposed Radiography 7000 M			
	Predicate Device: MobileDiagnost wDR 2.2 (K191813, SE date on August 2, 2019)	***Proposed Device: Radiography 7000 M (K233678)***	***Discussion & Conclusion***
Tube	E7886X used with 40kW Generator E7865X used with 20kW Generator	XRR-3331 - 0.6/1.2	Single tube configuration to address both adult and pediatric clinical use case. Hence no impact on clinical needs and safety of the device; Hence demonstrating substantial equivalence.
Material	Rhenium-Tungsten, Molybdenum	Rhenium-Tungsten faced Molybdenum	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Maximum tube voltage	150 kVp	150 kVp	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Nominal focal spot	E7886X- 0.7/1.3 E7865X- 0.3/1.0	XRR-3331 - 0.6/1.2	Single tube configuration to address both adult and pediatric clinical use case. Hence no impact on clinical needs and safety of the device; Hence demonstrating substantial equivalence.
Anode type	Rotating	Rotating	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Nominal anode input power	20kW, 40kW	20kW, 40kW	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Generators			
Power Configurations	20kW and 40kW	20kW and 40kW	No differences in characteristics between

Table 1: Comparison of the design feature of the currently marketed and predicate MobileDiagnost wDR 2.2 versus the proposed Radiography 7000 M			
	Predicate Device: MobileDiagnost wDR 2.2 (K191813, SE date on August 2, 2019)	***Proposed Device: Radiography 7000 M (K233678)***	***Discussion & Conclusion***
			subject and predicate device; Hence demonstrating Substantial Equivalence.
Column Configuration	Standard Column Sliding Column	Standard Column Sliding Column	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Exposure @ zero degree column position	Exposures are allowed when the column is at 0 Degree	Exposures are allowed when the column is at 0 Degree	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Exposure during Charging	Exposures are allowed when the unit is connected to mains (Note: exposure energy is drawn from generator batteries and not from mains)	Exposures are allowed when the unit is connected to mains (Note: Exposure energy is drawn from super caps which are powered by battery and not from mains.)	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Collimator			
Operation mode	Manual with light field indicator, multilayer, squared field	Manual Collimator with front and rear side knobs	External Connectivity This difference does not impact safety or effectiveness of the device; Hence demonstrating Substantial Equivalence
Collimator	Collimator with manual filter selection and no shutter position tracking	Collimator with motorized filters and manual shutter position tracking	This change will result in automatic Software calculation of DAP without additional hardware DAP device requirements. This difference does not impact the safety or effectiveness of the device. Hence demonstrating Substantial Equivalence.

Table 1: Comparison of the design feature of the currently marketed and predicate MobileDiagnost wDR 2.2 versus the proposed Radiography 7000 M			
	Predicate Device: MobileDiagnost wDR 2.2 (K191813, SE date on August 2, 2019)	***Proposed Device: Radiography 7000 M (K233678)***	***Discussion & Conclusion***
Shape of the beam	Rectangular	Rectangular	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Handles on Collimator	Handles can be used to move both Tube head and Collimator	Handles can be used to move both Tube head and Collimator	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
External Connectivity			
DICOM	DICOM compatible	DICOM compatible	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
Software Platform			
Application Software	Eleva Workspot Inc 41 with SkyFlow	Eleva Workspot Inc 43 with SkyFlow	Subject device software loaded with additional Features. This difference does not impact the safety or effectiveness of the device. Hence demonstrating Substantial Equivalence.
Image Processing Algorithm	UNIQUE 2	UNIQUE 2	No differences in characteristics between subject and predicate device; Hence demonstrating Substantial Equivalence.
PC	Intel® Core™ i5 based PC	Intel® Core™ i7 based PC, with SSD for better performance Place holder for 5G module	This difference does not impact the safety or effectiveness of the device. Hence demonstrating Substantial Equivalence.
DAP	Hardware DAP support	E-DAP (Software DAP) and Hardware DAP support	This difference does not impact the safety or

Table 1: Comparison of the design feature of the currently marketed and predicate MobileDiagnost wDR 2.2 versus the proposed Radiography 7000 M			
	Predicate Device: MobileDiagnost wDR 2.2 (K191813, SE date on August 2, 2019)	***Proposed Device: Radiography 7000 M (K233678)***	***Discussion & Conclusion***
			effectiveness of the device. Hence demonstrating Substantial Equivalence.
Indications For Use (IFU)	Intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures for the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with patient sitting, standing, or lying in the prone or supine positions. Not for mammography.	The Radiography 7000 M is intended for diagnostic procedures on both adult and pediatric patients who are unable to be transferred to the stationary X-ray system. It enables radiographic imaging of various body parts, including the skull, chest, spine, shoulders, pelvis, extremities, abdomen, and other body regions. The system allows for applications in different positions, such as sitting, standing, and lying in either a prone or supine position. However, it should be noted that the system is not suitable for mammography applications.	The wording: “patients who are unable to be transferred to the stationary X-ray system” has been newly added into proposed device Radiography 7000 M Indication for Use compared to the predicate device MobileDiagnost wDR 2.2. because both proposed device Radiography 7000 M and predicate device MobileDiagnost wDR 2.2 will be operated on patient that cannot be transferred to Fixed X-ray system. This aims to enhance user clarity and user understanding. This modification does not alter the operational similarity between proposed device Radiography 7000 M and its predicate device MobileDiagnost wDR 2.2, both capable of operating on non-transferrable patients. The inclusion of "shoulders" and "pelvis" in the documentation signifies additional clarity on its capabilities, but it is essential to note that these are illustrative

Table 1: Comparison of the design feature of the currently marketed and predicate MobileDiagnost wDR 2.2 versus the proposed Radiography 7000 M			
	Predicate Device: MobileDiagnost wDR 2.2 (K191813, SE date on August 2, 2019)	***Proposed Device: Radiography 7000 M (K233678)***	***Discussion & Conclusion***
			examples, not limitations. The device can be applied to various body parts beyond those explicitly mentioned. ***Conclusion:*** Based on the information and comparison presented above, it can be concluded that the Indications For Use of the proposed device Radiography 7000 M is substantially equivalent to the Indications For Use of the currently marketed and predicate device MobileDiagnost wDR 2.2.

The outcome of this comparison demonstrates that the modifications do not affect the safety or effectiveness of the proposed Radiography 7000 M when compared to the currently marketed and predicate MobileDiagnost wDR 2.2 (K191813 - August 2, 2019).

Summary of Non-Clinical and Clinical Performance Data:
This 510(K) premarket notification includes non-clinical performance testing.
Tests were performed on the proposed Radiography 7000 M according to the following FDA recognized standards and guidance documents: The verification and validation methods (test methods and acceptance criteria) used to evaluate the proposed Radiography 7000 M are the same as those used for the predicate device (K191813) and follow International and FDA recognized consensus standards and guidance documents applicable to this device type:

- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Recognition # 19-49)
- IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (Recognition # 19-36)
- IEC 60601-1-3 Edition 2.2 2021-01 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 (Recognition # 12-336)

- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (Recognition # 5-132)
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software - Software life cycle processes (Recognition # 13-79)
- IEC 62366-1 Edition 1.1 2020-06 CONSOLIDATED VERSION, Medical devices - Part 1: Application of usability engineering to medical devices (Recognition # 5-129)
- IEC 60601-2-54 Edition 2.0 2022-09, Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (Recognition # 12-348)
- IEC 60601-2-28 Edition 3.0 2017-06: Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis Recognition # 12-309
- ISO 14971:2019, Medical devices - Application of risk management to medical devices(Edition 3.0) Recognition # 5-125
- ISO 10993-1, Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (Recognition # 2-258)
- IEC 62220-1-3:2008 Edition 1.0 2008-06, Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging (Recognition # 12-214)
- IEC 60601-1-9:2007/AMD2:2020 Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design.
- NEMA PS 3.1 - 3.20 Digital Imaging And Communications In Medicine (DICOM) Set
- Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices, issued September 1, 2016
- Guidance for Content of Premarket Submissions for Device Software Functions, Issued on June 14, 2023.
- Guidance for Radio Frequency Wireless Technology in Medical Devices, issued on: August 14, 2013
- FCC Rules and Regulations CFR 47, Part 15, Subpart B (10-1-21 Edition)
- Guidance for Pediatric Information for X-ray Imaging Device Premarket Notifications, issued November 2017
- Guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions issued on September 27, 2023

The proposed device complies with the Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices. The solid-state imaging components including the detector in the proposed device have the same physical, functional, and operational characteristics as the predicate device (K191813). Also, other image chain components like X-ray tube and generator, which are used for exposure characteristics and clinical performance evaluation remain the same. Hence, all the features and characteristics potentially influencing image quality of the proposed are in accordance with FDA guidance document 'Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Devices, dated September 1, 2016'. Additionally, Image quality testing has been performed on the proposed device for the changes that are affecting the image quality.

The proposed device complies with the Guidance for Content of Premarket Submissions for Device Software Functions, Issued on June 14, 2023. The changes to the proposed device do not alter the intended use or the fundamental scientific technology when compared to the predicate device (K191813). The software for the

proposed device has the Enhanced documentation level. The software verification testing has been conducted as per the documentation level.

The proposed device complies with the Guidance for Pediatric Information for X-ray Imaging Device Premarket Notifications, issued November 2017. The changes made to the proposed device do not affect the pediatric application. The indication for use of the proposed device is the same as the predicate device (K191813).

The proposed device complies with Guidance for Radio Frequency Wireless Technology in Medical Devices, issued August 14, 2013 and FCC Rules and Regulations CFR 47, Part 15, Subpart B (10-1-21 Edition). The verification testing has been conducted for the safety and efficacy of the wireless components.

The proposed device complies with the Guidance for Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions issued on September 27, 2023. A set of cybersecurity controls to assure proposed device's cybersecurity and maintain medical device functionality and safety are in place. Cybersecurity plan and risk document are prepared to assess the proposed device for the following:

- Identification of assets, threats, and vulnerabilities;
- Assessment of the impact of threats and vulnerabilities on device functionality and end users/patients;
- Assessment of the likelihood of a threat and of a vulnerability being exploited;
- Determination of risk levels and suitable mitigation strategies;
- Assessment of residual risk.

Refer Table 2 for the non-clinical testing that were performed on the proposed device. Test results demonstrate that the proposed Radiography 7000 M meets acceptance criteria and is adequate for its intended use. Risk assessment activities show that the risks are sufficiently mitigated.

Table 2 Testing Summary for the changes on the proposed device

Tests	Test results
System Verification testing	Pass System verification test activities substantiate that the system conforms to the system requirements
Software verification testing	Pass Software verification test activities substantiate that the software conforms to the requirements
Risk control	Pass System meets the defined risk control measures
Cyber Security	Pass Results demonstrate that the test complies with the Cybersecurity requirements

There is no clinical data submitted in this 510(k) Premarket notification.

Substantial Equivalence Conclusion:

The proposed device, Radiography 7000 M is substantially equivalent to the currently marketed and predicate device, (K191813) in terms of the design features, technological characteristics, indications for use, and safety and effectiveness.

Additionally, substantial equivalence was demonstrated with non-clinical performance tests and testing as per FDA-recognized consensus standards. The test results demonstrate that the device conforms to its specifications and is safe and effective for its intended use.