U.S. FOOD & DRUG ADMINISTRATION

May 6, 2025

Solutions for tomorrow AB
℅ Martin Yngvesson
Coo
Saxagardsvagen 1
VACKELSANG, 36251
SWEDEN

Re: K241980
Trade/Device Name: !M1
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: December 3, 2024
Received: December 3, 2024

Dear Martin Yngvesson:

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

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

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

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

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

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

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

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

Sincerely,

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.

Submission Number *(if known)*

K241980

Device Name

!M1

Indications for Use *(Describe)*

The device is designed to perform general radiography x-ray examinations on all pediatric and all adult patients, in all patient treatment areas.

Treatment areas are defined as professional health care facility environments where operators with medical training are continually present during patients' examinations.

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.

1. Traditional 510 (k) SUMMARY

This 510(k) Traditional application is prepared according to the FDA guideline.

1.1 Submitter's Information

Name of manufacturer:	Solutions for tomorrow AB
Address:	Saxagårdsvägen 1 362 51 Väckelsång Sweden
Phone:	+46 10 456 4500
Official FDA contact:	Martin Yngvesson martin@solutionsfortomorrow.se +46 10 456 4502
Date Prepared:	May 30, 2024

1.2 Device Administrative Information

Device Trade Name:	!M1
Device Common Name:	mobile X-ray system
Classification Name:	Mobile X-ray system
Device Class:	Class II
Product Code:	IZL – 21 CFR 892.1720, System, X-ray, Mobile
Classification Panel:	Radiology

2. Legally Marketed Predicate Device

The following is the identified predicate device:

Solutions for tomorrow AB - K170607

Device Trade Name:	!M1
Device Common Name:	mobile X-ray system
Classification Name:	Mobile x-ray system
Device Class:	Class II
Product Code:	IZL – 21 CFR 892.1720, System, X-ray, Mobile
Classification Panel:	Radiology

The device is designed to perform general radiography x-ray examinations on all pediatric and all adult patients, in all patient treatment areas.

Treatment areas are defined as professional health care facility environments where operators with medical training are continually present during patients' examinations.

3. Device Description

The !M1 mobile X-ray system is a diagnostic mobile x-ray system utilizing digital radiography (DR) technology. The device consists of a self-contained x-ray generator, image receptor(s), imaging display and software for acquiring medical diagnostic images both inside and outside of a standard stationary x-ray room. The !M1 system incorporates a flat-panel detector(s) that can be used wirelessly for exams such as in-bed projections. The system can also be used to expose CR phosphor screens or film.

3.1 Indications for Use (Proposed Device)

The device is designed to perform general radiography x-ray examinations on all pediatric and all adult patients, in all patient treatment areas.

Treatment areas are defined as professional health care facility environments where operators with medical training are continually present during patients' examinations.

4. Substantial Equivalence Comparison and Discussion

The subject of this traditional 510(k) application is to add optional items of !M1 mobile X-ray unit that improve its performance (new automatic collimator, 40 kW and 400 mAs generator option, 133 kV X-ray tube). The subject of this traditional 510(k) is to add new detector lines manufactured by Canon Medical Systems and Konica Minolta. New detectors have smaller pixel size, better MTF and DQE values and the overall quality of acquired images is better. With this application we also integrate imaging software and detectors manufactured by Vieworks. By having more options of software and detectors we can provide a wide range of configurations to answer customer needs in a better way.

Table 1. !M1 mobile X-ray unit

Parameter	Predicate Device	Subject Device	Equivalence
510(k) number	K170607		
Manufacturer	Solutions for tomorrow AB	Solutions for tomorrow AB	Equivalent
Device Name	!M1	!M1	Equivalent
Regulation Number	21 CFR 892.1720	21 CFR 892.1720	Equivalent
Common Name	Mobile X-ray system	Mobile X-ray system	Equivalent
Classification Name	Mobile X-ray system	Mobile X-ray system	Equivalent
Product Code	IZL	IZL	Equivalent
Device Class	Class II	Class II	Equivalent
Indications for use	The device is designed to perform general radiography x-ray examinations on all pediatric and all adult patients, in all patient treatment areas. Treatment areas are defined as professional health care facility environments where operators with medical training are continually present during patients' examinations.	The device is designed to perform general radiography x-ray examinations on all pediatric and all adult patients, in all patient treatment areas. Treatment areas are defined as professional health care facility environments where operators with medical training are continually present during patients' examinations.	Equivalent
Collimator	Manual, single layer	Motorized, single layer	MODIFIED
Max kV	125 kV	133 kV	MODIFIED
Max mAs	320 mAs	400 mAs	MODIFIED
Max kW	32 kW	40 kW	MODIFIED

Table 2. Konica Minolta Software and detectors

Parameter	Predicate Device	Subject Device	Equivalence
Manufacturer	Konica Minolta	Konica Minolta	Equivalent
Device Name	SKR 3000	SKR 3000	Equivalent
510(k)	K113248, K130936, K141271, K162504	K223267	MODIFIED
Indications for Use	This device is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen system in general-purpose diagnostic procedures. This device is not indicated for use in mammography, fluoroscopy, and angiography applications.	This device is indicated for use in generating radiographic images of human anatomy. It is intended to replace radiographic film/screen system in general-purpose diagnostic procedures. This device is not indicated for use in mammography, fluoroscopy, and angiography applications.	Equivalent
Operator Console	CS-7	CS-7	Equivalent
DR Detectors	P-21 – AeroDR 1717HQ P-31 – AeroDR 1012HQ P-51 – AeroDR2 14171HQ P-61 – AeroDR 3	P-81 P-65 P-75 P-82 P-85 P-95	MODIFIED
DQE	P-21, P-31, P-51: 65% 0 cycle/mm P-61: 51% 1 cycle/mm	P-81, P-65, P-75, P-82, P-85, P-95: 72% 0 cycle/mm	MODIFIED
MTF	P-21, P-31, P-51: 55% 1 cycle/mm P-61: 53% 1 cycle/mm	P-81, P-65, P-75, P-82, P-85, P-95: 62% 1 cycle/mm	MODIFIED
Pixel size	P-21: 175 µm P-31: 175 µm P-51: 175 µm P-61: 100/200 µm	P-81, P-65, P-75, P-82, P-85, P-95: 100/200 µm	MODIFIED

Table 3. Canon image software and detectors

Parameter	Predicate Device	Subject Device	Equivalence
Manufacturer	Canon Inc.	Canon Inc.	Equivalent
Device Name	Digital Radiography, Solid State X-ray Imager	Digital Radiography CXDI-CS01	MODIFIED
510(k)	K133693, K131106	K230175	MODIFIED
Indications for Use	The digital radiography detectors provide digital image capture for conventional film/screen	The Digital Radiography CXDI-CS01 provides digital image capture for conventional film/screen	Equivalent

	systems in all general purpose diagnostic procedures. These devices are not intended for mammography applications.	radiographic examinations. This device is intended to capture, for display, radiographic images of human anatomy, and to replace radiographic film/screen systems in all general purpose diagnostic procedures. This devices is not intended for mammography applications.	
Operator Console	CXDI Control Software	CXDI Control Software	Equivalent
DR Detectors	CXDI-701C Wireless CXDI-401C Wireless CXDI-801C Wireless	CXDI-720C Wireless CXDI-420C Wireless CXDI-820C Wireless CXDI-Pro: CXDI-703C Wireless CXDI-403C Wireless CXDI-803C Wireless CXDI-Elite: CXDI-720C Wireless CXDI-420C Wireless CXDI-820C Wireless	MODIFIED
DQE	CXDI-701C Wireless, CXDI-401C Wireless, CXDI-801C Wireless: 0.6 @ 0 lp/mm	CXDI-702C Wireless: 58% [@0.5 lp/mm, 1 mR] CXDI-402C Wireless: 58% [@0.5 lp/mm, 3.5 uGy] CXDI-710C Wireless, CXDI-810C Wireless, and CXDI410C Wireless: 60% [@0 lp/mm, 4 uGy] CXDI-Pro: 58% [@0.5 lp/mm, 3.5 uGy] CXDI-Elite: 67% [@0.5 lp/mm, 3.5 uGy]	MODIFIED
Pixel size	CXDI-701C Wireless, CXDI-401C Wireless, CXDI-801C Wireless: **125µm**	CXDI-702C Wireless, CXDI-402C Wireless, CXDI-710C Wireless, CXDI-810C Wireless, CXDI-410C Wireless, and CXDI-Elite: **125µm**	MODIFIED

		CXDI-Pro: **140 µm**	
Spatial resolution	CXDI-701C Wireless, CXDI-401C Wireless, CXDI-801C Wireless: 0.35 @ 0 lp/mm	CXDI-702C Wireless, CXDI-402C Wireless, CXDI-710C Wireless, CXDI-810C Wireless, CXDI-410C Wireless, and CXDI-Pro: **35% [MTF@2lp/mm]** CXDI-Elite: 45% **[MTF@2lp/mm]**	MODIFIED

Table 4. Vieworks image software and detectors.

Parameter	**Predicate Device**	**Subject Device**	**Equivalence**
Manufacturer		Vieworks Co., Ltd	MODIFIED
Device Name		VIVIX-S FW, VIVIX-S VW	MODIFIED
510(k)		K221512, K200418	MODIFIED
Indications for Use		The VIVIX detectors are used for general purpose diagnostic procedures, and as well as intended to replace radiographic film/screen systems. They are not intended for mammography applications.	MODIFIED
Operator Console		VXvue	MODIFIED
DR Detectors		FXDR-4343FAW FXDR-3643FAW FXDR-2530FAW FXDR-4343VAW, FXDR-4343VAW PLUS, FXDR-3643VAW, FXDR-3643VAW PLUS, FXDR-2530VAW, FXDR-2530VAW PLUS	MODIFIED
DQE (measured values at 1 lp/mm)		FXDR-4343FAW: 45 FXDR-3643FAW: 41.5 FXDR-2530FAW: 46 FXDR-4343VAW: 45, FXDR-4343VAW PLUS: 53, FXDR-3643VAW: 41.5, FXDR-3643VAW PLUS: 51, FXDR-2530VAW: 46, FXDR-2530VAW PLUS: 52	MODIFIED
MTF (measured value at 1lp/mm)		FXDR-4343FAW: 76 FXDR-3643FAW: 74	MODIFIED

		FXDR-2530FAW: 76 FXDR-4343VAW: 76, FXDR-4343VAW PLUS: 60, FXDR-3643VAW: 74, FXDR-3643VAW PLUS: 59, FXDR-2530VAW: 76, FXDR-2530VAW PLUS: 52	
Pixel size		FXDR-4343FAW, FXDR-3643FAW, FXDR-2530FAW: **99 µm** FXDR-4343VAW, FXDR-4343VAW PLUS, FXDR-3643VAW, FXDR-3643VAW PLUS: **140 µm** FXDR-2530VAW, FXDR-2530VAW PLUS: **124 µm**	MODIFIED
Spatial resolution		FXDR-4343FAW: 5 lp/mm FXDR-3643FAW: 5 lp/mm FXDR-2530FAW: 4 lp/mm FXDR-4343VAW/FXDR-4343VAW PLUS: 3.5 lp/mm, FXDR-3643VAW/FXDR-3643VAW PLUS: 3.5 lp/mm, FXDR-2530VAW/FXDR-2530VAW PLUS: 4 lp/mm	MODIFIED

5. Non-clinical testing

Integration testing comprising the !M1 system, Vieworks VXvue operation console and detectors (FXDR-VAW, FXDR-VAW Plus and FXDR-FAW) demonstrates that the implementation was successfully performed. The new collimator and the upgraded performance of the generator (40 kW and 400 mAs generator option), and X-ray tube (133 kV) has been successfully verified and found in compliance with applicable standards.

5.1 Compliance with Standards

!M1 mobile X-ray unit comply with the following standards:

EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes

EN ISO 14971:2020 Medical devices – Application of risk management to medical devices

EN ISO 10993-1:2009 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

EN ISO 15223-1:2016 Medical devices – Symbols to be used with medical device lavels, labelling and information to be supplied – Part 1: General requirements

EN 60601-1:2021 Ed 3.1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

EN 60601-1-2:2015 Ed 4.0 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests

EN 60601-1-3:2008 + A1:2013 Medical electrical equipment for basic safety and essential performance – Collateral standard: Radiation protection in diagnostic X-ray equipment

EN 60601-2-28:2010 Ed 2.0 Medical electrical equipment – Part 2-28: Particular requirements for the safety and essential performance of X-ray tube assemblies for medical diagnosis

EN 60601-2-54:2009 Ed 1.0 Medical Electrical Equipment - Part 2: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy

EN 62304:2015 Medical devices software – Software life cycle processes

EN 62366-1:2015 Medical devices – Application of usability engineering to medical devices

6. Conclusion

!M1 mobile X-ray unit with new options and wider image software and detectors selection has the same intended use, technology, materials, and uses most of the same components as the predicate device. The changes to the subject device have little to no impact on the safety or performance device (improved generator and X-ray tube characteristics only improve the performance of the device) and no additional questions regarding safety or effectiveness have been raised. The fundamental scientific technology of the subject device included in this submission remains unchanged from the legally marketed predicated device (K170607). Therefore, the proposed device is substantially equivalent to the predicate device.