October 24, 2025

Solutions for tomorrow AB
% Martin Yngvesson
Project manager
Saxagårdsvägen 1
Väckelsång
SWEDEN 36251

Re: K251710
Trade/Device Name: Mobile X-ray unit (!M1)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: June 30, 2025
Received: September 23, 2025

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,

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

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)*
K251710

Device Name
Mobile X-ray unit (!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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Solutions for tomorrow

October 24, 2025

510 (k) Summary

!M1 Mobile X-ray Unit

K251710

1. Submitter Information

Name of manufacturer:	Solutions for tomorrow AB
Address:	Saxagårdsvägen 1 36251 Väckelsång Sweden
Phone:	+46 10 456 4500
Official FDA contact:	Martin Yngvesson martin@solutionsfortomorrow.se +46 10 456 4502
Correspondent contact:	Nan Jin njin@dms-imaging.com +33 78 848 6797

2. Device Information

Device Trade Name:	Mobile X-ray Unit (!M1)
Device Common Name:	System, X-ray, Mobile
Classification Name:	Mobile x-ray system
Regulation Number:	21 CFR 892.1720
Product Code:	IZL
Device Class:	Class II
Classification Panel:	Radiology

3. Legally Marketed Predicate Device

The following is the identified predicate device:

Manufacturer:	Solutions for tomorrow AB
510(k) Number:	K241980
Device Trade Name:	Mobile X-ray Unit (!M1)
Device Common Name:	Mobile x-ray system
Classification Name:	Mobile x-ray system
Regulation Number:	21 CFR 892.1720
Product Code:	IZL
Device Class:	Class II
Classification Panel:	Radiology

4. Device Description Summary

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.

5. Intended Use/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.

6. Substantial Equivalence Comparison and Discussion

6.1 Indications for Use Comparison

The indications for use are the same as for the predicate device.

6.2 Technological Comparison

The subject of this Traditional 510(k) application is to integrate a new imaging system (including imaging software and flat panel detectors) manufactured by JPI Healthcare and an additional display monitor option. The introduced changes enhance the user experience and answer customer needs in a better way.

Table 1. !M1 mobile X-ray unit

Parameter	Predicate Device	Subject Device	Equivalence
510(k) number	K241980	K251710	/
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	System, X-ray, Mobile	System, X-ray, Mobile	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 healthcare 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 healthcare facility environments where operators with medical training are continually present during patients' examinations.	EQUIVALENT
Collimator	Manual or Motorized, single layer	Manual or Motorized, single layer	EQUIVALENT
Imaging system (including software and detector) Compatibility	Konica Minolta imaging system Or Canon imaging system Or Vieworks imaging system	Konica Minolta imaging system Or Canon imaging system Or Vieworks imaging system Or JPI Healthcare imaging system	MODIFIED

Display monitor	17”	17” or 18.5”	MODIFIED

Table 2. Integrated and compatible imaging system

Parameter	Predicate Device	Subject Device	Equivalence
Konica Minolta Imaging system			**NO CHANGE**
Device Name	SKR 3000	SKR 3000	EQUIVALENT
Manufacturer	Konica Minolta	Konica Minolta	EQUIVALENT
510(k)	K223267	K223267	EQUIVALENT
Canon Imaging system			**NO CHANGE**
Device Name	Digital Radiography, Solid State X-ray Imager	Digital Radiography, Solid State X-ray Imager	EQUIVALENT
Manufacturer	Canon Inc.	Canon Inc.	EQUIVALENT
510(k)	K230175	K230175	EQUIVALENT
Vieworks Imaging system			**NO CHANGE**
Device Name	VIVIX-S FW, VIVIX-S VW	VIVIX-S FW, VIVIX-S VW	EQUIVALENT
Manufacturer	Vieworks Co., Ltd	Vieworks Co., Ltd	EQUIVALENT
510(k)	K221512, K200418	K221512, K200418	EQUIVALENT
JPI Healthcare Imaging system			**ADDITION**
Device name		ExamVue Apex	MODIFIED
510(k)		K244010	MODIFIED
Software Manufacturer		JPI Healthcare Co, Ltd	MODIFIED
Detector Manufacturer		Thales	MODIFIED
Indications for Use		The ExamVue Apex flat panel x-ray detector system is indicated for use in general radiology, specialist radiology including podiatry, orthopedic, and other specialties, and in mobile x-ray systems. The ExamVue Apex flat panel x-ray detector system is not indicated for use in mammography.	MODIFIED
Acquisition and Control Software		ExamVue Duo (K213057)	MODIFIED
Detector Models		EVA 10W EVA 14W EVA 17W	MODIFIED
Detector Type		Amorphous Silicon	MODIFIED
Scintillator		CsI	MODIFIED
Pixel Pitch		99 µm	MODIFIED

Solutions for tomorrow AB
Address: Saxagårdsvägen 1, S-362 51 Väckelsång, SWEDEN
Phone: +46 10 456 45 00
Email: info@solutionsfortomorrow.se
Web: http://www.solutionsfortomorrow.se

DQE		73 % [@0 lp/mm, 6µGy] / 70% [@0 lp/mm, 2µGy]	MODIFIED
Spatial Resolution		68% [MTF@1 lp/mm]	MODIFIED
Wireless Communication		Wifi (802.11ac/ax) or cable	MODIFIED

Table 3. Display monitors

Parameter	Predicate Device	Subject Device	Equivalence
510(k) number	K241980	K251710	/
Type	17": TFT – LCD LED backlight	17": TFT – LCD LED backlight 18.5": TFT – LCD LED backlight	MODIFIED
Active screen size	17": 432.75mm diagonal	17": 432,75mm diagonal 18.5": H408.96 * V230.04 mm	MODIFIED
Pixel format	17": H1280* V1024	17": H1280* V1024 18.5": H1920* V1080	MODIFIED
Color depth	17": 16.7M colors	17": 16.7M Colors 18.5": 16.7M Colors	MODIFIED
White luminance (monitor only)	17": 400 cd/m2 (Center 1 Point, Typ.)	17": 400 cd/m2 (Center 1 Point, Typ.) 18.5": Typ. 350 cd/m2	MODIFIED
White luminance (with touch)	17": 350 cd/m2	17": 350 cd/m2 18.5": 300 cd/m2 Min.	MODIFIED
Viewing angle	17": R/L 179° (type.), U/D 178° (type.) for CR<10	17": R/L 179° (type.), U/D 178° (type.) for CR<10 18.5": R/L 89°, U/D 89°	MODIFIED

Solutions for tomorrow AB
Address: Saxagårdsvägen 1, S-362 51 Väckelsång, SWEDEN
Phone: +46 10 456 45 00
Email: info@solutionsfortomorrow.se
Web: http://www.solutionsfortomorrow.se

Contrast ratio	17”: 1000:1	17”: 1000:1 18.5”: 1000:1	MODIFIED
Touch type	17”: Capacitive	17”: Capacitive 18.5”: Capacitive	MODIFIED

7. Non-clinical Tests Summary

Integration testing comprising the !M1 system and ExamVue Apex imaging system demonstrates that the implementation was successfully performed. The new display monitor option has been thoroughly verified and meets all applicable standards.

7.1 Compliance with Standards

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

- IEC 62304 Edition 1.1 2015-05 CONSOLIDATED VERSION Medical devices software – Software life cycle processes
- 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
- IEC 60601-2-28 Edition 3.0 2017-06 Medical electrical equipment – Part 2-28: Particular requirements for the safety and essential performance of X-ray tube assemblies for medical diagnosis
- 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
- 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
- IEC 60601-1 Edition 3.2 2020-08 CONSOLIDATED VERSION Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 62366-1 Edition 1.0 2015-02 Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 15223-1 Fourth Edition 2021-07 Medical devices – Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
- ISO 10993-1 Fifth Edition 2018-08 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

- ISO 14971 Third Edition 2019-12 Medical devices – Application of risk management to medical devices
- ISO 13485 Third Edition 2016-03 Medical devices – Quality management systems – Requirements for regulatory purposes

7.2 Followed FDA Guidance

- Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff - June 2023
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions - Guidance for Industry and Food and Drug Administration Staff - June 2025
- Pediatric Information for X-ray Imaging Device Premarket Notifications - Guidance for Industry and Food and Drug Administration Staff - November 2017
- Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment - Guidance for Industry and Food and Drug Administration Staff - October 2023
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" - Guidance for Industry and Food and Drug Administration Staff – September 2023
- General Principles of Software Validation - Guidance for Industry and FDA Staff – January 2002
- Off-The-Shelf Software Use in Medical Devices - Guidance for Industry and Food and Drug Administration Staff – August 2023
- Applying Human Factors and Usability Engineering to Medical Devices - Guidance for Industry and Food and Drug Administration Staff – February 2016
- Content of Premarket Submissions for Device Software Functions - Guidance for Industry and Food and Drug Administration Staff – June 2023

8. Conclusion

The !M1 mobile X-ray device with new imaging system and additional display monitor option 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, 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 (K241980). Therefore, the proposed device is substantially equivalent to the predicate device.