April 18, 2025

ECORAY Co., Ltd.
℅ Jay Mansour
Mansour Consulting LLC
845 Aronsom Lake Court
ROSWELL, GA 30075

Re: K241996
Trade/Device Name: Ultra 1040
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: February 20, 2025
Received: February 20, 2025

Dear Jay Mansour:

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,

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)*
K241996

Device Name
ULTRA 1040

Indications for Use *(Describe)*

The ULTRA 1040 Portable X-ray Unit is a portable X-ray device, intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the patient's extremities.

This device is not intended for mammography.

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.

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510(k) Summary

K241996

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92

Date: April 15, 2025

1. INFORMATION

1.1. Submitter Information

Submitter Name:	ECORAY Co., Ltd.
Address:	(04778) #714~716, ForHu B/D, 58, Wangsimni-ro, Seongdong-gu, Seoul, Republic Of Korea
Telephone Number:	Tel: +82-70-7510-3407
Email:	ra@ecoray.kr

1.2. Official Correspondent

Name:	Mr. Jay Mansour
Company Name	Mansour Consulting LLC
Address:	845 Aronson Lake Court. Roswell, GA 30075
Telephone Number:	Tel: +1 (678) 908-8180
Email:	Email: jay@mansourconsulting.com

2. DEVICE INFORMATION

Trade Name:	ULTRA 1040
Common Name:	System, X-ray, Mobile
Classification Name:	Mobile x-ray system
Product Code:	IZL
Classification Regulation:	21 CFR Part 892.1720
Device Class:	II

3. PREDICATE DEVICE

Manufacturer:	Shantou Institute of Ultrasonic Instruments Co., Ltd. (SIUI)
Trade Name:	SR-8100
Common Name:	System, X-ray, Mobile
Classification Name:	Mobile x-ray system
Product Code:	IZL
Classification Regulation:	21 CFR Part 892.1720
Device Class:	II
510(k) Number:	K200637

4. SUBJECT DEVICE DESCRIPTION

This Portable X-ray Unit (Model: ULTRA 1040) consists of the following major components: an X-ray main unit, an X-ray exposure hand switch and a battery charger and other components. The X-ray main unit is mainly for emitting X-rays required for X-ray exams; the hand switch is for output control of X-ray emitting, and the battery charger is for charging the built-in battery in the X-ray main unit. The device can be used with an X-ray detector, a computer for receiving and detecting signal results and image processing software. The major components of the X-ray main unit include: handle, enclosure, control panel, system control board, high-voltage tank, collimator (beam limiter), lithium-ion battery and system control software running on the system control board.

The system control software is for real-time interaction and control with various circuit modules inside the portable X-ray unit. The software responds to user operations on the control panel. The user can adjust and control the kV and mAs parameters, and the software will display the parameters or directly load the APR parameters. The software loads the control data from X-ray output into the high-voltage generation control circuit of the system control board and control the high-voltage tank to generate high-voltage to excite the ray tube inside to emit X-rays, control the switch of the collimator indicator, and monitor the working status of the device, the battery power status, and control the display of the status indicators.

5. INDICATIONS FOR USE

The ULTRA 1040 Portable X-ray Unit is a portable X-ray device, intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the patient's extremities.

This device is not intended for mammography.

6. SUBSTANTIAL EQUIVALENCE

6.1. Comparison Chart of Features and Specifications

Item	Proposed Device	Predicate Device	
K Number	K241996	K200637	
Manufacturer	ECORAY Co., Ltd.	SIUI	
Trade Name	ULTRA 1040	SR-8100	
Device Classification Name	Mobile x-ray system	Mobile x-ray system	Same
Product Code	IZL	IZL	Same
Regulation Number	21CFR892.1720	21CFR892.1720	Same
510(k) Review Panel	Radiology	Radiology	Same

Item	Proposed Device	Predicate Device	
Indication for use	The ULTRA 1040 Portable X-ray Unit is a portable X-ray device, intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the patient's extremities. This device is not intended for mammography.	The SR-8100 Portable X-ray Unit is a portable X-ray device, intended for use by a qualified/trained physician or technician for the purpose of acquiring X-ray images of the desired parts of patient's anatomy (including head, cervical spine, chest, abdomen, lumbar spine, pelvis and extremities). The device may be used for handheld diagnostic imaging of body extremities. The system is subject to the following limitations of use when stand-mounted: The device may be used for diagnostic imaging of head, cervical spine, abdomen, lumbar spine, pelvis or extremities. The device may be used for imaging of the chest when used without a grid. This device is not to be used on bariatric patients, unless imaging body extremities. This device is not intended for mammography.	Similar
Principle of Operation	General Purpose Diagnostic X ray	General Purpose Diagnostic X ray	Same
Size	384 x 227.5 x 199 mm	227 x 522 x 217 mm	Similar
Weight	12 kg (Including Collimator)	12kg (Including Collimator)	Same
Energy source	Lithium Polymer Battery (58.8 VDC) Charging voltage : 100V ~ 240~V, 50/60 Hz, 80VA 250 exposure per charge	Lithium-ion Rechargeable Battery (29.6VDC), 300 exposures per charge.	Similar
Use Interface	Soft touch push buttons	Soft touch push buttons	Same
Exposure times	0.008 sec – 2.5 sec	0.02 sec – 2.5 sec: R'10 sec Step	Similar
Tube current [mA]	40~50kV/ 40mA 51~60kV/ 35mA 61~70kV/ 30mA 71~80kV/ 30mA 81~90kV/ 25mA 91~100kV/ 20mA	25 mA @ 40kVDC – 60kVDC (1kVP steps) 20 mA @ 61kVDC – 100kVDC (1kVP steps)	Similar

Item		Proposed Device	Predicate Device	
		● All 1kV steps		
Tube Voltage Range [kVp]		40 - 100kVp, 61 Step (1kV Step)	40 - 100kVp, 61 Step (1kV Step)	Same
Memory settings		10 Memories	5 memories	Slightly high
HF Generator		High frequency	High frequency	Same
Output power [kW]		2.4kW	2.0 kW	Slightly high
X-ray Tube		OX/100-L (C.E.I.)	D-125SB	Different
Collimator		Double slit type and manually operation with LED Light indicator	SIUI SR-8100-19L	Different
Focal Spot Size		• 1.0mm	• 1.2mm	Similar
Anode Heat Storage Capacity		• 19,600 HU (14000J)	• 50,000HU (35,000J)	Different
FDA Performance Standard		• Complies	• Complies	Same
X-ray switching frequency		• 100kHz	• 100kHz	Same
Control		• 2 Point Control (kV, mAs)	• 2 Point Control (kV, mAs)	Same
Anatomical Programs		• Preprogrammed 12or 7 APR data - User Programmable	• Preprogrammed 9 APR data-User Programmable	Similar
Collimator	Model	ULTRA 1040BT Collimator	SR-8100-19L	-
	Manufacturer	ECORAY Co.,Ltd.	SIUI	-
	Control	30 sec Lamp timer	Manual with 15, 30, 45, 60 sec. Lamp timer	Similar
	Field Shape	Rectangular	Rectangular	Same
	Max. Field Size	35x35 cm (at 66cm SID)	44x44cm (at 100cm SID)	Different
	Inherent Filtration	0.58 mmAl	1.2mmAl	Similar
	Standard	Rotating flange	Rotating flange	Same

Item		Proposed Device	Predicate Device	
	Option	Tape measure (Max.200cm)	Tape measure (Max.200cm)	Same
	Electrical Rating	3.25 VDC, 10 W	3-12VDC,10W	Similar
Performance standard		• IEC 60601-2-28:2017 • IEC 60601-2-54:2022	• IEC 60601-2-28:2010 • IEC 60601-2-54:2015	Similar
Electrical safety		• IEC 60601-1:2005/ AMD1:2012/AMD2:2020 • IEC 60601-1-2:2014/ AMD1:2020 • IEC 60601-1-3:2008/ AMD1:2013/AMD2:2021 • IEC 62304:2006/AMD1:2015 • IEC 60601-1-6:2010/ • AMD1:2013/AMD2:2020 • IEC 62366-1:2015, IEC 62366-1:2015/AMD1:2020	• IEC 60601-1:2012 • IEC 60601-1-2:2014 • IEC 60601-1-3:2013 • IEC 60601-1-6:2015 • IEC 62304:2006+AMD1:2015 • IEC 62366-1:2015/COR1:2016	Similar
Compatible X-ray Detector		• Device trade name : VIVIX-S VW • Model Name : FXRD-3643VAW • Manufacture : VIEWORKS Co., LTD • 510(k) Number : K200418	-	

6.2. The difference between the subject device and the predicate device

The predicate device is intended for acquiring X-ray images of the patient head, cervical spine, abdomen, lumbar spine, pelvis and extremities, while the subject device is intended for diagnostic imaging of body extremities.

The differences in specific limitations (e.g., stand-mounted restrictions, use on bariatric patients) do not significantly alter the primary intended use of the device, which is to perform diagnostic imaging on a range of anatomical regions for medical purposes. Thus, the ULTRA 1040 can be seen as having the same fundamental intended use as the SR-8100, without constituting a new intended use.

Other differences between ULTRA 1040 and SR-8100 include differences in collimator and X-ray Tube. But the above differences are inherent characteristics of device. The tube current and tube voltage range are similar to predicate device.

And Size, Weight, Energy source, Exposure times, Performance standard, Electrical safety are also similar to predicate device, but they are not items that significantly affect performance, and their intended use is equivalent.

The proposed device, ULTRA 1040 has been tested for electrical safety, EMC, software and Li-ion polymer battery pack has been validated.

7. SUMMARY OF NON-CLINICAL TESTING

Testing was performed in accordance with the following international standards:

No.	Test Items	Standards
1	Medical electrical equipment Part 1: General requirement for basic safety and essential performance	IEC 60601-1:2005/AMD2:2020
2	Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment	IEC 60601-1-3:2008+A2:2021
3	Medical electrical equipment Part 1-6: General requirements for safety – Collateral standard: Usability	IEC 60601-1-6:2010+AMD2:2020
4	Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	IEC 60601-2-28: 2017
5	Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	IEC 60601-2-54:2022
6	Medical electrical equipment Part1-2: General requirements Section1.2 Collateral standard: Electromagnetic compatibility	IEC 60601-1-2:2014/AMD1:2020
7	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems	IEC 62133-2:2017
8	Safety of laser products - Part 1: Equipment classification and requirements	IEC 60825-1:2007
9	Diagnostic x-ray system and their major components	21 CFR 1020.30
10	Radiographic Equipment	21 CFR 1020.31
11	Medical device software - Software life cycle processes	IEC 62304:2006/A1:2015

7.1. Safety, EMC and Performance Data

Electrical, mechanical, environmental safety and performance testing were conducted according to standard IEC 60601-1, IEC 60601-1-3, IEC 60601-1-6, IEC 60601-2-28, IEC 60601-2-54 and EMC testing was conducted according to IEC 60601-1-2. All test results were satisfying with the standards.

7.2. Bench Performance Testing

The bench test for the Ultra 1040 Portable X-ray Unit assessed radiation performance, collimator accuracy, battery performance, imaging quality, and safety. The Ultra 1040 Portable X-ray Unit met bench testing acceptance criteria as defined in the test protocols. This testing supports substantial equivalence of the Ultra 1040 technological characteristics and performance compared to the predicate device.

7.3. Software

The following tests were performed to assess effectiveness of software of the device. The test was performed in accordance with following standards.

No.	Test Items	Standards
1	Medical device software - Software life cycle processes	IEC 62304:2006/A1:2015

8. SUMMARY OF CLINICAL PERFORMANCE TESTING

A comprehensive, task-based image quality study was conducted to assess the clinical adequacy of the device's imaging performance.

This study collected radiographic images for relevant anatomical indications stated in the Indications for Use.

Images were acquired for standing mounted imaging. Radiologic technologists acquired images in all acquisition modes with appropriately selected techniques, and radiologist clinically evaluated the image quality.

9. SPECIFIC GUIDANCE DOCUMENT

All applicable aspects of these guidance documents listed in this 510(k) summary have been addressed. The device also conforms to the following:

- 21 CFR 1020 Subchapter J: Performance Standards for Ionizing Radiation Emitting Products,
- 21 CFR 1020.30: Diagnostic x-ray systems and their major components,
- 21 CFR 1020.31: Radiographic Equipment

Furthermore, the following Specific Guidance Document was utilized in the device development to ensure the safety of this device for both the operators and patients:

- **Content of Premarket Submissions for Device Software Functions** *Guidance for Industry and Food and Drug Administration Staff* **June 2023**
- **Guidance for the Submission of 510(k)s for Solid State X-ray Imaging Devices** *Guidance for Industry and Food and Drug Administration Staff* **September 2016**
- **Pediatric Information for X-ray Imaging Device Premarket Notifications** ***Guidance for Industry and Food and Drug Administration Staff*** **November 2017**

10. CONCLUSIONS

Under the comparing substantial equivalence between the subject devices and the predicate devices, there are the same points such as general information, some technical and material information. Although there are some differences, the safety and performance test reports support the safety and effectiveness of the subject device. In this regard, we conclude that the subject device is substantially equivalent to the predicate device.