



May 28, 2025

Livermoretech Inc
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group LLC
7505 Fannin St. Suite 610
HOUSTON, TX 77054

Re: K244049

Trade/Device Name: Europa (Alternative: AiRTouch) portable X-ray system
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile X-Ray System
Regulatory Class: Class II
Product Code: IZL
Dated: April 29, 2025
Received: April 29, 2025

Dear Dave Kim:

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,

 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
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Enclosure

Indications for Use

510(k) Number (if known)

K244049

Device Name

Europa (Alternative: AiRTouch) portable X-ray system

Indications for Use (Describe)

Europa (Alternative: AiRTouch) portable X-ray system is intended for use by trained or qualified doctors to produce diagnostic X-ray images of extremities in adult and pediatric (over 12 years old) patients. These images are obtained using anatomical structures captured by film or image processing systems (workstation) after an examination involving radiation exposure with cassette IP, CR, or DR (portable flat panel). Only intended for stand-mounted use.

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
K244049**

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

Date 510k summary prepared: April 23, 2025

I. SUBMITTER

Submitter's Name	Livermoretech Inc.
Submitter's Address	801 North Jupiter Rd, Suite 200 Plano TX 75074
Submitter's Telephone	
Contact person	Casey Lee (casey.lee@aspenimaging.com) / VP Manager Tel: +1-214-257-0113
Official Correspondent	Dave Kim, MBA (davekim@mtechgroupllc.com)
Address	Mtech Group LLC 7505 Fannin St. Ste 610, Houston, TX 77054
Telephone	+713-467-2607

II. DEVICE

Trade/proprietary Name	Europa (Alternative: AiRTouch) Portable X-ray System
Model Name	Europa 85,85L, 90, 90L (Alternative: AiRTouch 855, 855L, 905, 905L)
Regulation Name	Mobile X-ray System
Regulation Number	21 CFR 892.1720
Product Code	IZL
Regulatory Class	Class II

III. PREDICATE DEVICE

510K Number	K193535
Manufacturer	Livermoretech Inc.
Device Name	EZER Portable X-ray System
Regulation Name	Mobile X-ray System
Regulation Number	21 CFR 892.1720
Product Code	IZL
Regulatory Class	Class II

IV. DEVICE DESCRIPTION:

EUROPA(Alternative: AiRTouch) portable X-ray System generates X-ray with variable tube current and voltage (kVp) to take diagnostic X-rays of extremities for adult and pediatric patients. It operates on 22.2VDC supplied by a rechargeable Lithium-Ion Polymer battery pack. The X-ray tube head, X-ray controls and power source are assembled into a single portable X-ray enclosure. EUROPA(Alternative: AiRTouch) portable X-ray System includes high voltage generator, X-ray tube, a control board (PCB), rechargeable battery, LCD user interface, X-ray beam limiting device, and a remote-control switch (hand switch). Operating principle is that x-ray generated by high voltage electricity into x-ray tube, which penetrates patients’ extremities and makes x-ray images on receptor. EUROPA(Alternative: AiRTouch) Portable X-ray System is intended to be used by trained clinicians or technicians for both adult and pediatric(over 12 years old) patients.

EUROPA(Alternative: AiRTouch) portable X-ray is intended to be mounted on a tripod stand.

V. Indications for Use: 21 CFR 807 92 (a) (5)

Europa (Alternative: AiRTouch) portable X-ray system is intended for use by trained or qualified doctors to produce diagnostic X-ray images of extremities in adult and pediatric(over 12 years old) patients. These images are obtained using anatomical structures captured by film or image processing systems (workstation) after an examination involving radiation exposure with cassette IP, CR, or DR (portable flat panel). Only intended for stand-mounted use.

Comparison Table with the Predicate Device for technological characteristics:

Feature	Europa (Alternative: AiRTouch) Portable X-ray System	EZER Portable X-ray System
510K No	K244049	K193535
Indications for Use/Intended Use:	Europa(Alternative: AiRTouch) portable X-ray system is intended for use by trained or qualified doctors to produce diagnostic X- ray images of extremities in adult and pediatric(over 12 years old) patients. These images are obtained using anatomical structures captured by film or image processing systems (workstation) after an examination involving radiation exposure with cassette IP, CR, or DR (portable flat panel). Only intended for stand-mounted use.	EZER Portable X-Ray system is a portable x-ray source with a fixed tube current and voltage for producing diagnostic x-ray images of extremities using digital or film image receptors. Its use is intended to be used by trained clinician or technicians for both adult and pediatric subjects age 2 and above. It is not intended to replace a radiographic system with variable tube current and voltage (kVp) which may be required for full optimization of image quality and radiation exposure for difference exam types.
Principle of Operation	General Purpose Diagnostic X-Ray	General Purpose Diagnostic X Ray

TECHNOLOGICAL:			
Size: Body	Europa 85 (Alternative: AiRTouch 855)	266mm (W) x 167mm (H) x 156mm (D)	9.2" L x 6.4"W x 4.6" H
	Europa 85L (Alternative: AiRTouch 855L)	266mm (W) x 167mm (H) x 156mm (D)	
	Europa 90 (Alternative: AiRTouch 905)	367mm (W) x 201mm (H) x 188mm (D)	
	Europa 90L (Alternative: AiRTouch 905L)	293.5mm (W) x 171mm (H) x 160.5mm (D)	
Weight	Europa 85 (Alternative: AiRTouch 855)	3.61kg	2.6kg (5.7 lbs.)
	Europa 85L (Alternative: AiRTouch 855L)	3.5kg	
	Europa 90 (Alternative: AiRTouch 905)	4.9kg	
	Europa 90L (Alternative: AiRTouch 905L)	3.7kg	
Source to skin distance	30 cm	30 cm	
Focal Spot	Europa 85 (Alternative: AiRTouch 855)	0.8mm	1.2 mm
	Europa 85L (Alternative: AiRTouch 855L)	0.8mm	
	Europa 90 (Alternative: AiRTouch 905)	0.5mm	
	Europa 90L (Alternative: AiRTouch 905L)	0.5mm	
Collimator	Double slit type, manually operated steplessly adjustable shutters	Four manually and steplessly adjustable shutters with light beam type central x-ray indicator (Advantech R72)	
Triggering Mechanism	Two stage triggering	Two stage triggering	
User Interface	Up-down push buttons for kVp selections and exposure time selections with LED indicators and mAs indicators.	Up-down push buttons for kVp selections and exposure time selections with LED indicators and mAs indicators.	
Energy Source	Rechargeable 22.2 V DC, 2200mAh Lithium Ion Polymer battery pack	Rechargeable 22.2 V DC Lithium Ion Polymer battery pack	
Exposure Time	Europa 85 (Alternative: AiRTouch 855)	0.03 ~ 2.0 Sec. (0.01 step)	0.03~1.30 seconds in 0.01 increments

	Europa 85L (Alternative: AiRTouch 855L)	0.03 ~ 2.0 Sec. (0.01 step)		
	Europa 90 (Alternative: AiRTouch 905)	0.04 ~ 1.3 Sec. (0.01 step)		
	Europa 90L (Alternative: AiRTouch 905L)	0.04 ~ 1.3 Sec. (0.01 step)		
mA			2.0 mA fixed	
	Europa 85 (Alternative: AiRTouch 855)	2~5 mA (1mA step)		
	Europa 85L (Alternative: AiRTouch 855L)	2~5 mA (1mA step)		
	Europa 90 (Alternative: AiRTouch 905)	2~5 mA (1mA step)		
	Europa 90L (Alternative: AiRTouch 905L)	2~5mA (1mA step)		
kVp			60 kVp fixed	
	Europa 85 (Alternative: AiRTouch 855)	50~85 kV (1kV step)		
	Europa 85L (Alternative: AiRTouch 855L)	50~85 kV (1kV step)		
	Europa 90 (Alternative: AiRTouch 905)	50~90 kV (1kV step)		
	Europa 90L (Alternative: AiRTouch 905L)	50~90 kV (1kV step)		

VI. Discussion of differences

The subject device is similar to the predicate device in terms of the indications for use and technological application. Both the subject and predicate devices are portable X-ray system for taking diagnostic X-rays of patients' extremities.

The subject device enables the user to select the power and exposure time manually whereas the power settings of the predicate device are fixed. Other differences include device design such as battery pack, exposure time, size and user interface.

VII. Summary of Clinical and Non-clinical testing

Testing was performed successfully according to the following standards:

- IEC 60601-1: 2020, Ed 3.2, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2020, Ed 4.1 IEC 60601-1-3:2008+A1:2013 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances
- IEC 60601-1-3: 2021, Ed 2.2, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment

- IEC 60601-2-28: 2017, Ed 3.0, Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
- IEC 60601-2-54:2022, Ed 2.0 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- IEC 62133:2012, Ed 2.0, 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 [Including: Corrigendum 1 (2013)]

Clinical images taken with EUROPA 85 and EUROPA 90 have presented overall appropriate image quality of the anatomical structures, both bony and soft tissues of the upper and lower extremities.

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:

“Radiation Safety Consideration for X-ray Equipment Designed for Hand-Held Use”

“The Content of Premarket Submissions for Software Contained in Medical Devices”

“Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”

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 system and their major components

21 CFR 1020.31: Radiographic Equipment

VIII. Conclusion:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided above comparison table, the EUROPA(Alternative: AiRTouch) Portable X-ray Systems have little difference with its size and user interface as the information in the table. The subject device is substantially equivalent to the predicate device with its intended use, mechanical and electrical performance as described.

Performance evaluation (test) reports and the device inspection report confirmed that the EUROPA(Alternative: AiRTouch) Portable X-ray Systems are suitable for its intended use and the instructions for use.