September 20, 2024

Energy Resources International Co., Ltd.
℅ Pearl Tsai
QA & RA Specialist
2F.-5, No.6-1, Sec.2, Shengyi Rd., Zhubei City
Hsinchu County, 302058
TAIWAN

Re: K234108
Trade/Device Name: ERI Portable X-ray System (CVX-air); ERI Portable X-ray System (CVX-lite); ERI Portable X-ray System (CVX-E)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: December 22, 2023
Received: December 27, 2023

Dear Pearl Tsai:

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 (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 located 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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 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 Part 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 Radiologic 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)*

K234108

Device Name

ERI Portable X-ray System (CVX-air);
ERI Portable X-ray System (CVX-lite);
ERI Portable X-ray System (CVX-E)

Indications for Use *(Describe)*

ERI Portable X-ray System is a portable x-ray source with a fixed tube current and voltage for producing x-ray images of extremities using computed radiography (CR) detection plate or digital radiography (DR) detector, and the applicable objects are adults. This product is for use by qualified personnel.
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 different exam types.

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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The assigned 510(K) number: K234108
Date Prepared: 07/22/2024

I. Submitter Information

Submitter:
ENERGY RESOURCES INTERNATIONAL CO., LTD.
Address: 2F.-5, No.6-1, Sec.2, Shengyi Rd., Zhubei City, Hsinchu County 302058, Taiwan (R.O.C)
Phone Number: +886-3-6585156
Fax Number: +886-3-6585802

Primary Contact Person: Pearl Tsai
Email: pearl.tsai@eriray.com
Phone Number: +886-3-6585156 ext.112
Fax Number: +886-3-6585802

Secondary Contact Person: Robert Yang
Email: robert@eriray.com
Phone Number: +886-3-6585156 ext.100
Fax Number: +886-3-6585802

II. Subject Device

Trade Name: ERI Portable X-ray System (CVX-air),
ERI Portable X-ray System (CVX-lite),
ERI Portable X-ray System (CVX-E)
Model: CVX-air, CVX-lite, and CVX-E
Common Name and Classification:

No.	Product Code	Common Name	Regulatory Class	Regulation Number	Panel
1	IZL	Mobile x-ray system	II	21 CFR 892.1720	Radiology

III. Predicate Device

Subject Device	Predicate Device		
	Predicate Device	**Submitter/510(k) Holder**	**510(k) Number**
	EZER Portable X-ray System	Livermoretech	K193535

IV. Device Description

ERI Portable X-ray System generates and controls X-ray with a fixed tube current and voltage (kV). It uses X light source to produce X-ray images of human anatomical structures for diagnosis, and the applicable objects are adults. It operates on 14.4VDC supplied by a rechargeable Lithium-Ion Polymer battery pack.

The ERI Portable X-ray System, is a portable x-ray device that comes in three models: CVX-air, CVX-lite and CVX-E. The differences is as follows:

Diversity Description	Main Model	Series Model	
	CVX-air	CVX-lite	CVX-E
X-ray tube voltage	70kV	67 kV	60 kV
X-ray tube current	1mA	0.8mA	0.6mA
Power Consumption	70 W	53.6 W	36W
Others are the same as CVX-air The main model and series models have the same internal and external appearance, only the X-ray irradiation parameter settings are different			

The X-ray tube head, X-ray controls and power source are assembled in a portable case. The ERI Portable X-ray System is comprised of the following components:

(1) X-ray module

(2) Oscillating circuit board

(3) Control board

(4) Beam limiting device

(5) LCD screen

(6) Extension wire control

(7) rechargeable battery.

V. Indications for Use

ERI Portable X-ray System is a portable x-ray source with a fixed tube current and voltage for producing x-ray images of extremities using computed radiography (CR) detection plate or digital radiography (DR) detector, and the applicable objects are adults. This product is for use by qualified personnel.

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 different exam types.

VI. Comparison of Technology Characteristics with the Predicate Device

Energy Resources International claims that the ERI Portable X-ray System is substantially equivalent to the EZER Portable X-ray System cleared by the FDA in K193535. Energy Resources International claims substantial equivalence because the CVX-air, CVX-lite and CVX-E has a similar intended use, operating principles, and operational specifications as compared to the predicate device.

The specific details regarding the similarities and differences between the ERI Portable X-ray System and EZER Portable X-ray System have been identified and explained in the Comparison Table, see table below. A summary of these similarities and differences is included below. These differences do not present any new issues related to safety and effectiveness.

Device name	**EZER Portable X-ray System (Predicate Device: K193535)**	**ERI Portable X-ray System (Proposed Device)**
Classification, regulation number, product code	Mobile x-ray system, 21 CFR 892.1720, IZL	Mobile x-ray system, 21 CFR 892.1720, IZL

Indications for Use/Intended 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 different exam types.	ERI Portable X-ray System is a portable x-ray source with a fixed tube current and voltage for producing x-ray images of extremities using computed radiography (CR) detection plate or digital radiography (DR) detector, and the applicable objects are adults. This product is for use by qualified personnel. 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 different exam types.
TECHNOLOGICAL		
Size: Body	9.2" L x 6.4" W x 4.6" H	147(H)×211.1(W)×161.7(D) mm
Weight	2.6 kg	3.2 kg
Source to skin distance	30 cm	45 cm
Focal Spot	1.2 mm	0.45 mm
Collimator	Four manually and steplessly adjustable shutters with light beam type central x-ray indicator (Advantech R72)	Stepless manual button control, using a motor to drive the light gate to adjust the X-ray irradiation range.
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 exposure time selection to adjust mAs, LED on/off buttons, and collimator horizontal/vertical control buttons.
Energy Source	Rechargeable 22.2 V DC Lithium Ion Polymer battery pack	Rechargeable 14.4 V DC Lithium Ion Polymer battery pack
Exposure Time	0.03~1.30 seconds in 0.01 increments	0.01~1.00 seconds in 0.01 increments
mA	2.0 mA fixed	1.0 mA fixed / 0.8 mA fixed / 0.6 mA fixed
kVp	60 kVp fixed	70 kVp fixed / 67 kVp fixed / 60 kVp fixed

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 human anatomy using a fixed tube current and voltage (kVp). Other differences in device design such as exposure time, size, and user interface.

VII. Non-clinical Test Data

Testing was performed in accordance with the following international standards:

- IEC 62304 Edition 1.1 [2015-06] Medical device software - Software life cycle processes
- IEC 60601-1 Edition 3.2 [2020-08 CONSOLIDATED VERSION] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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 Compatibility - Requirements And Tests
- 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 60601-2-54 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
- ISO14971 Third Edition [2019-12] Medical devices - Applications of risk management to medical devices
- 21 CFR 1020.30: Diagnostic x-ray system and their major components
- 21 CFR 1020.31: Radiographic Equipment

VIII. Clinical Performance Data

The ERI Portable X-ray System has undergone comprehensive non-clinical design verification and validation testing, including assessments of Electrical Safety and performance. The results confirm that the device's design is appropriate and effective for its intended use. Additionally, clinical trials were conducted to compare the imaging results of the ERI Portable X-ray System with those obtained from commercially available X-ray devices. These trials demonstrated that the image quality produced by the ERI system is on part with that of the comparison devices, supporting its substantial equivalence as a portable X-ray system.

IX. Conclusions

The Energy Resources International ERI Portable X-ray System has the same intended use and same basic technology as the predicate device, thus is able to achieve the same effectiveness and safety as the predicate device. The ERI Portable X-ray System contains in some combination similar features and design as the predicates. Other differences include device design such as exposure time, size and user interface. The subject device is substantially equivalent to the predicate device with its intended use, mechanical and electrical performance as described.