Livermoretech, Inc.
℅ Mr. Dave Kim
Regulatory Affairs
Mtech Group
7707 Fannin Street, Suite 200
HOUSTON TX 77054

May 7, 2020

Re: K193535
Trade/Device Name: EZER, 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 17, 2020
Received: April 17, 2020

Dear Mr. 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 (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.

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.

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193535

Device Name
EZER
Portable X-ray System

Indications for Use *(Describe)*

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.

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
K193535

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

Date 510k summary prepared: April 29, 2020

I. SUBMITTER

Submitter's Name	Livermoretech
Submitter's Address	801 North Jupiter Rd, Suite 200 Plano TX 75074
Submitter's Telephone	
Contact person	Jay Kim (jay.kim@aspenstate.com) / RA Manager Tel: +1-214-257-0113
Official Correspondent	Dave Kim (davekim@mtech-inc.net)
Address	7707 Fannin St. Ste 200, V111, Houston, TX 77054
Telephone	+713-467-2607

II. DEVICE

Trade/proprietary 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

III. PREDICATE DEVICE

510K Number	K140723
Manufacturer	Aribex, Inc
Device Name	NOMAD MD Handheld X-ray System
Regulation Name	Mobile X-ray System
Regulation Number	21 CFR 892.1720
Product Code	IZL
Regulatory Class	Class II

LIVERMORETECH
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IV. DEVICE DESCRIPTION:

EZER Portable X-ray System generates and controls X-ray with a fixed tube current and voltage (kVp) in order to take diagnostic X-rays of extremities for adult and pediatric patients. It operates on 22.2VDC supplied by a rechargeable Lithum-Ion Polymer battery pack. The X-ray tube head, X-ray controls and power source are assembled into a single hand-held enclosure. EZER Portable X-ray System includes high voltage generator, X-ray tube, a control board (PCB), rechargeable battery, LCD user interface, X-ray beam limiting cone, and a remote control switch (hand switch). Operating principle is that x-ray generated by high voltage electricity into x-ray tube, which penetrates extremities and makes x-ray images on receptor. INTEL stick PC is integrated with EZER so the user can see X-ray image from LCD display without a computer. EZER Portable X-ray System is intended to be used by trained clinicians or technicians for both adult and pediatric patients.
The embedded 7" TFT display in EZER Portable X-ray is not intended to be used for diagnosis.

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

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.

Comparison Table with the Predicate Device for technological characteristics:

Feature	Nomad MD X-ray System (K140723)	EZER Portable X-ray System (K193535)
Regulation No.	21 CFR 892.1720	21 CFR 892.1720
Regulation Class	II	II
Product Code	IZL	IZL
Indications for Use/Intended Use:	The NOMAD MD is a handheld and portable general purpose X-ray system. The device uses a fixed tube current and voltage (kVp) and, therefore, is limited to taking diagnostic X-rays of extremities. It is intended to be used by a qualified and trained clinician on both adult and pediatric patients. 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.	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.
Principle of Operation	General Purpose Diagnostic X-Ray	General Purpose Diagnostic X Ray
TECHNOLOGICAL:		
Size: Body	9.5”H x 5.25”Wx10”L (excluding Source Skin guard)	9.2” L x 6.4”W x 4.6” H
Weight	11.0 lbs.	5.7 lbs (2.6 kg)
Source to skin distance	30 cm	30 cm
Focal Spot	0.4 mm	1.2 mm
Collimator	Four manually and steplessly adjustable shutters with LED Light Field Center Indicator	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 buttons for exposure time selection, with timer display.	Up-down push buttons for kVp selections and exposure time selections with LED indicators and mAs indicators.
Energy Source	Rechargeable 14.4 V DC NiCd battery pack	Rechargeable 22.2 V DC Lithium Ion Polymer battery pack
Exposure Time	0.02 – 0.99 seconds in 0.01 increments	0.03~1.30 seconds in 0.01 increments
mA	2.0 mA fixed	2.0 mA fixed
kVp	75 kVp fixed	60 kVp fixed

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 human anatomy using a fixed tube current and voltage (kVp). The subject device has on board computer and a display screen that allows the doctor to view X-ray images for reference purpose only and not for diagnosis. Other differences include device design such as battery pack, exposure time, size and user interface.

VII. Non clinical testing

Testing was performed successfully according to the following standards:

- IEC 60601-1-3:2008+A1:2013
- EN 60601-1-2:2015
- IEC 62133:2012
- EN 62133:2013
- EN 60601-1:2006/A1:2013
- IEC 60601-2-54:2009 (First edition),A1:2014 for use in conjunction with IEC 60601-1:2015 (third e dition) A1:2012

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"

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. Summary of Clinical Tests

Images taken from the predicate and subject devices were reviewed and rated in comparison by an American board-certified radiologist.
Based on image comparison test and data analysis, images taken from EZER, the subject device, have similar quality overall compared with Nomad MD, the predicate device. Based on images taken from EZER, there are no other radiographic abnormalities and any issue with diagnostic images.

IX. 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 EZER Portable X-ray System has 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 device inspection report confirmed that the EZER Portable X-ray System suitable for its intended use and user instruction of the device.