



December 19, 2019

LIVERMORETECH, Inc.
% Mr. Dave Kim
Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

Re: K190935

Trade/Device Name: EZER, Portable X-ray System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: EHD
Dated: November 20, 2019
Received: November 20, 2019

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,

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

Indications for Use

510(k) Number (if known)

K190935

Device Name

EZER

Portable X-ray System

Indications for Use (Describe)

EZER Portable X-Ray system is intended to be used by trained dentists and dental technicians as an extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

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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LIVERMORETECH

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K190935

510(k) Summary

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

Date 510k summary prepared: Nov 15, 2019

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@aspensate.com) / RA Manager Tel: +1-214-257-0113
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II. DEVICE

Trade/proprietary Name	Portable X-ray System
Model Name:	EZER
Common or Usual Name	Portable X-ray System
Regulation Name	Extra-oral Source X-Ray System
Regulation Number	21 CFR 872.1800
Product Code	MUH
Regulatory Class	Class II

III. PREDICATE DEVICE

510K Number	K134055
Manufacturer	Dexcowin Co., Ltd
Device Name	ADX 4000W; iRay D4
Regulation Name	Extra-oral Source X-Ray System
Regulation Number	21 CFR 872.1800
Product Code	EHD
Regulatory Class	Class II

IV. DEVICE DESCRIPTION:

EZER Portable X-ray System generates and controls X-ray in order to diagnose of tooth and jaw. 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 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 tooth and jaw 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 dentists or dental technicians. Its use is intended for both adult and pediatric subjects.

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 intended to be used by trained dentists and dental technicians as an extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects.

Technological characteristics: 21 CFR 807 92 (a) (6) Comparison Table

FEATURE	DEXCOWIN ADX 4000W (K134055)	LIVERMORETECH EZER (NEW)
	The ADX4000W Cordless Portable Dental X-Ray System is indicated for use only by trained and qualified dentists or dental technicians for both adult and pediatric subjects for taking diagnostic extraoral dental X-ray digital sensors.	EZER Portable X-Ray system is intended to be used by trained dentists and dental technicians as an extraoral x-ray source for producing diagnostic x-ray images using intraoral image receptors. Its use is intended for both adult and pediatric subjects
Size	240(L) x 166(W) x 82(H) [mm] (9.4" x 6.5" x 3.2")	233.5(L) x 162.9(W) x 116.9(H) [mm] 9.2" x 6.4" x 4.6"
Weight	2.4 kg	2.6 kg
Total filtering	Over 1.5mmAl (inherent filtration : 0.8mmAl)	Over 1.5mmAl (inherent filtration : 0.8mmAl)
Cone diameter	7 cm	6 cm
User interface	Up-down buttons for exposure time selection with timer display. Additionally, several user-selectable preset times with patient size and tooth selection icons on an LCD display	Up-down buttons for exposure time selection with timer display.
Backscatter radiation protection	6.3" dia. Pb-filled acrylic plastic scatter shield	6.3" dia. Pb-filled acrylic plastic scatter shield

Exposure switch	Exposure button at x-ray control panel	Exposure button at back cover on right hand side, or a remote control switch
Tube head mounting	Handheld, or on a tripod	Handheld, or on a tripod
CPU	1.6 Ghz	Intel Atom x5 Z8300 Processor (1.84 Ghz)
Display	4.8 inch Touch Panel TFT-LCD (1024x600)	7 inch TFT LCD Panel (Resolution : 1024 x 600)
Energy source	Rechargeable 22.2 V DC Lithium Polymer battery pack	Rechargeable 22.2 V DC Lithium Ion Polymer battery pack
Exposure time	0.05 ~ 1.35 seconds in 0.01 increments	0.03~1.30 seconds in 0.01 increments
Time Accuracy	$\pm (10\% + 1 \text{ ms})$	$\pm (10\%)$
mA	2 mA fixed	2 mA fixed
kVp	65 kV fixed	60 kV fixed
Waveform	Constant Potential (DC)	Constant Potential (DC)

VI. Discussion of differences

The subject device is identical to the predicate device in terms of the indications for use and type of energy source. Both devices have on board computer and a display screen that allows the doctor to view dental X-ray images. The differences are device design, size and user interface.

VII. Non clinical testing

Testing was performed successfully according to the following standards:

- IEC 60601-1-3:2008+A1:2013
- IEC 60601-2-65:2012
- EN 60601-2-65:2013
- 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 edition) + A1:2012
- IEC 61000-4-3: 2006 + A2: 2010

Test for proximity fields from RF wireless communications 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:

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

“The Content of Premarket Submissions for Software Contained in Medical Devices”
“Content of Premarket Submission for Management of Cybersecurity in Medical Devices”
“Radio Frequency Wireless Technology in Medical Device Guidance for Industry and FDA Staff”

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 EZER Portable X-ray System has little difference with its size and user interface as the information in the table. But the system is substantially equivalent to the predicate devices with its design, 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.