March 31, 2022

Aspenstate, Inc.
% Mr. Dave Kim
Regulatory Affairs
Mtech Group
7505 Fannin St, Suite 610
HOUSTON TX 77054

Re: K220678
Trade/Device Name: APX-24 Portable X-ray System
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: Class II
Product Code: IZL
Dated: February 28, 2022
Received: March 8, 2022

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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-ray Systems Team
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220678

Device Name
APX-24 Portable X-ray System

Indications for Use *(Describe)*

The APX-24 Portable X-ray is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic X-rays.

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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ASPENSTATE, INC
801 North JupiterRd, Suite 200, Plano, TX 70574 USA
Tel.: +214-257-0113

510(k) Summary

This summary of 510(k) information is submitted following the requirements of 21 CFR Part 807.92.

Date 510k summary prepared: February 28, 2022

I. SUBMITTER

Submitter's Name	Aspenstate, Inc
Submitter's Address	801 North Jupiter Rd, Suite 200 Plano TX 75074
Submitter's Telephone Contact person	Albert Kim/Managing Director albert.kim@aspenstate.com Tel: +1- 214-257-0113
Official Correspondent Address Telephone	Dave Kim (davekim@mtech-inc.net) 7505 Fannin St, Suite 610, Houston, TX 77054 +713-467-2607

II. DEVICE

Trade/Device Name:	APX-24 Portable X-ray System
Regulation Number:	21 CFR 892.1720
Regulation Name:	Mobile x-ray system
Regulatory Class:	II
Product Codes:	IZL
Common/Usual Name:	Digital Mobile Diagnostic X-Ray System

III. PREDICATE DEVICE

Trade/Device Name:	MinXray HF100H+^{TM}
510(k) Number:	K052721
Regulation Number:	21 CFR 892.1720
Regulation Name:	Mobile x-ray system
Regulatory Class:	II
Product Codes:	IZL
Common/Usual Name:	Digital Mobile Diagnostic X-Ray System

ASPENSTATE, INC
801 North JupiterRd, Suite 200, Plano, TX 70574 USA
Tel.: +214-257-0113

IV. DEVICE DESCRIPTION:

The APX-24 Portable X-ray is a portable unit that operates from120 V / 220-240V, 50 / 60 Hz. The unit utilizes a newly designed high-frequency inverter and can bemounted to a tripod or support arm. The operator must observe the usual safety precautions regarding the use of x- rays.

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

The APX-24 Portable X-ray is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic X-rays.

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

Characteristic	MinXray HF100H (K052721)	Aspenstate APX-24
Intended Use:	Intended for use by a qualified/trained physician or technician on both adultand pediatric subjects for talking diagnostic x-rays.	The APX-24 Portable X-ray is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic X-rays.
Size/weight	406 x 222 x 241 mm18.6kgs	414 x 230 x 215.5mm, 12.7kg
Energy Source	100-140V 50-60 HzAC3 OkVA	120VAC/220-240VAC, 50/60Hz
Mountingmethod	Unit is usually mounted to a MinXray XGS MKIII Portable Stand	This unit is not mounted to a Portable Stand
User Interface	Up-Down pushbuttons forkVp selections and exposure time selections with LED indictors and mAs indicators	Up/Down pushbuttons for kVp selections and exposure time selections with LED indicators
Exposure switch	Dual-stage, deadman type	Dual-stage, deadman type
Controls	Software-based, 2 CPUs.	Software-based, 2 CPUs.
Construction	Monobloc HF a generator, Medical full-bridge inverter system	Monoblock HF a generator, Medical full-bridge inverter system
High Voltage Energy Source	High frequency (60kHz) inverter	High frequency (102kHz) inverter
Line Voltage adjustment	Automatic, dynamic	Automatic, dynamic

Exposure times	0.03-0.2 sec(in 0.01 sec. Steps) 0.2-04 sec(in 0.02 sec. Steps) 04-1.0 sec(in 0.05 sec. Steps) 1.0-4.0 sec(m 0.1 sec. Steps)	0.03-0.2 sec(in 0.01 sec. Steps) 0.2-04 sec(in 0.02 sec. Steps) 04-1.0 sec(in 0.05 sec. Steps) 1.0-4.0 sec(m 0.1 sec. Steps)
Tube potential(kV)	40 - 100kV 2kVstep	40-100kV (1kV step)
kV steps	31(2kV-step)	31(2kV-step)
Tube current(mA)	30mA(40-60 kV) 25mA(62-80 kV) 20mA(82-100 kV)	30 mA (40-50 kV) 30, 35, 40 mA (51-60 kV) 25, 30 mA (61-70 kV) 15, 20, 30 mA (71-80 kV) 13, 25 mA (81-90 kV) 10, 20 mA (91-100 kV)
mA steps	Constant	Constant
X-ray tube	Canon D-124S	Canon D-125SB
Anode heatStorage	20,000HU	50,000 HU
Focal SpotSize	1.2 mm	1.2 mm
mAs	0.6-120mAs	0.32-100mAs
Total filtration	3.2mm AL equivalent	Min 2.8 mm AL
Collimator	Advantech R72 Continuously adjustable light beam type with central x-ray indicator	Continuously adjustable light beam type with central x-ray indicator
Source to Skin Distance (SSD)	300 mm	300 mm
Performance Standard	21CFR 1020.30	IEC60601-1-3, IEC60601-1-6, IEC60601-2-28, IEC60601-2-54 21CFR 1020.30, 21CFR 1020.31
Electrical safety	UL2601, IEC60601-1	IEC60601-1

VI. Discussion of differences

The subject device is similar to the predicate device regarding the indications for use and technological application. The subject and predicate devices are portable X-ray systems for taking diagnostic X-rays of human anatomy using a fixed tube current and voltage (kVp).

The differences are the device appearance, size, and user interface.

VII. Nonclinical 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
- EN 61000-3-2:2014
- EN 61000-3-3:2013
- 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

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:
"The Content of Premarket Submissions for Software Contained in Medical Devices"

VIII. Conclusion:

By the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided above comparison table, the APX-24 Portable X-ray System has little difference with its size and user interface as the information in the table. However, the system is substantially equivalent to the predicate devices with its design, mechanical and electrical performance as described.

Performance evaluation (test) reports and the device inspection report confirmed that the APX-24 Portable X-ray System is suitable for the device's intended use.