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

April 3, 2020

Re: K200022
Trade/Device Name: FLUSION-9001 Fluoroscopic C-arm Mobile X-ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, OXO, JAA, IZI
Dated: December 31, 2019
Received: January 6, 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)*

K200022

Device Name
FLUSION-9001
Fluoroscopic C-arm Mobile X-ray System

Indications for Use *(Describe)*

The FLUSION-9001 fluoroscopic C-arm Mobile X-ray System is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but are not limited to digital subtraction angiography, orthopedic, neurological, abdominal, vascular, cardiac, critical care and emergency room procedures.

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
K200022

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

Date 510k summary prepared: April 1, 2020

I. SUBMITTER

Submitter's Name	Livermoretech
Submitter's Address	801 North Jupiter Rd, Suite 200 Plano TX 75074
Submitter's Telephone	Tel: +1-214-257-0113
Contact person	Jay Kim (jay.kim@aspenstate.com) / RA Manager
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	FLUSION-9001 Fluoroscopic C-arm Mobile X-ray System
Regulation Name	Image Intensified Fluoroscopic Mobile X-ray System
Regulation Number	21 CFR 892.1650
Product Code	OWB, OXO, JAA, IZI
Regulatory Class	Class II

III. PREDICATE DEVICE

510K Number	K032761
Manufacturer	United Radiology Systems, Inc
Device Name	KMC-950
Regulation Name	Image Intensified Fluoroscopic Mobile X-ray System
Regulation Number	21 CFR 892.1650
Product Code	OWB, OXO, JAA
Regulatory Class	Class II

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IV. REFRENCE DEVICE

510K Number	K180473
Manufacturer	ECOTRON Co., Ltd
Device Name	ANYVIEW DR SERIES FPD Fluoroscopic Mobile C-Arm
Regulation Name	Image Intensified Fluoroscopic Mobile X-ray System
Regulation Number	21 CFR 892.1650
Product Code	OWB, OXO, JAA
Regulatory Class	Class II

V. DEVICE DESCRIPTION:

The FLUSION-9001 fluoroscopic C-arm Mobile X-ray System consists of a high voltage (HV) inverter generator, a tube support unit, an X-ray beam limiting device, mobile cart, a detector, operating software, and a tube, and is primarily used in a hospital for diagnosis of diseases in skeletal, respiratory and urinary systems such as the skull, spinal column, chest, abdomen, extremities, and other body parts. This device is not intended to be used for mammography applications.

FLUSION-9001 fluoroscopic C-arm Mobile X-ray System is a solution to produce radiological images of patient during medical operations. This inverter control X-ray unit visualizes the anatomical structure on screen, which is obtained by X-ray fluoroscopy and a flat panel detector. This system can be applied in emergency room, operation room, cast room or etc. of a hospital.

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

The FLUSION-9001 fluoroscopic C-arm Mobile X-ray System is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but are not limited to digital subtraction angiography, orthopedic, neurological, abdominal, vascular, cardiac, critical care and emergency room procedures.

Comparison Table with the Predicate Device for technological characteristics:

	Predicate device	Proposed device	SE
Model Name	KMC-950	FLUSION-9001 Fluoroscopic C-arm Mobile X-ray System	
510(k) Number	K032761	K200022	
Indications for Use	The KMC-950 is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but are not limited to digital subtraction angiography,	The FLUSION-9001 fluoroscopic C-arm Mobile X-ray System is intended to provide fluoroscopic and radiographic imaging of the patient during diagnostic, surgical and interventional procedures. Clinical applications may include but	Similar

		orthopedic, neurological, abdominal, vascular, cardiac, critical care and emergency room procedures. The system may be used for other RF imaging application at physician's discretion.	are not limited to digital subtraction angiography, orthopedic, neurological, abdominal, vascular, cardiac, critical care and emergency room procedures.	
X-ray Tube	Anode Type	Rotating	Rotating	Same
	Heat Capacity	300,000 HU	300,000 HU	Same
	Anode Heat Cooling	70kHU/min	60kHU/min	Similar
	Focal size	0.3mm / 0.6mm	0.3mm / 0.6mm	Same
Fluoroscopic Mode	kV range	40 to 125 kV See below discussion for differences	40 to 120 kV See below discussion for differences	Similar
	mA range	0.5 to 5 mA. See below discussion for differences	0.2 to 8mA. See below discussion for differences	Similar
	Pulse Fluoro	Yes	Yes	Same
	ABS function	Yes	Yes	Same
Detector	Manufacturer	Imaging Intensifier: Thales (TH9428HP2) Image Intensifier	Imaging Intensifier: E5830SD-P4A (TOSHIBA) Cleared under K160065	
	Size	9″	9″	Same
	Magnification	9″ / 6″ / 4.5″	9″ / 6″ / 4.5″	Same
	DQE	65	65 (@ 0 lp/mm)	Same
Camera	Type	½″ CCD	½″ CCD	Same
	Active pixels	512 x 512	1024 x 1024	Better
C-arm	Manufacturer	GEMSS medical	Livermoretech Inc.	
	SID	950mm	1000mm	Similar
	Range of C-ram Rail Rotation	115°	135°	Wider
	Range of the Liner FR-arm Movement	200 mm	200 mm	Same
	Range of the Linear T-arm Movement	500 mm	500 mm	Same
	Range of Swing-arm Rotation	± 12.5°	± 15°	Wider
	Range of Stay-arm Rotation	360°	190°	
Collimator	Collimator	Motor control / rotation	Motor control / rotation	Same

FPD Image Detector Comparison

		Subject Device	Subject Device	Subject Device	Reference Device
Model		VIVIX-D 1212G	Pixium® Surgical 3030S-A	3030DXV	VIVIX-D 1212G
510(k) No		K180473	K182086	K132904	K180473
Detector type		TFT	TFT	TFT	TFT
Active detector size		12 x 12 in	12 x 12 in	12 x 12 in	12 x12 in
Total pixel matrix		2048 x 2048	1956 x 1956	1536 x 1536	2048 x 2048
Pixel pitch		145 µm	154.0 µm	194.0 µm	145 µm
Frame rate		30 fps @ 2x2	30 fps	30 fps	30 fps @ 2x2
MTF	1.0 lp/mm	60%	55%	55%	60%
DQE	0 lp/mm	69%	75%	80%	69%

VII. Discussion of differences

The indications for use, operating principle, technical specifications such as X-ray tube head, image intensifier and FPD of FLUSION-9001 fluoroscopic C-arm Mobile X-ray System are similar to those of the predicate device (K032761) and reference device (K180473). FLUSION-9001 Fluoroscopic C-arm Mobile X-ray System is designed as a set of components (X-ray tube and housing, detector, digital imaging system, collimator, generator etc.) similar to the predicate device KMC-950 (K032761). All digital flat panel detectors available for the subject device have been cleared by FDA as a part of a complete fluoroscopy system (K180473, K182086, K132904). Based on the recognized standard conformity evidences related to electro-, mechanical-, software-, and risk management, Livermoretech certifies that technological characteristics of FLUSION-9001 fluoroscopic C-arm Mobile X-ray System are substantially equivalent to KMC-950, the predicate device. FLUSION-9001 Fluoroscopic C-arm Mobile X-ray System consists of many critical parts same as KMC-950, the predicate device (Collimator, X-ray imager, digital image processing and viewing program, C-arm, etc.).

FLUSION-9001 Fluoroscopic C-arm Mobile X-ray System utilizes PVCARM Viewer, a radiological digital image communications system. It provides one or more capabilities relating to the acceptance, transfer, display, storage, and digital processing of medical images. The software components provide functions related to simple manipulation, enhancement or quantification of images.

- PVCARM receives images from a detector, processes and transfers the images and manages patient's information and the images for doctor. PVCARM enables images such as x-ray images to be stored electronically and viewed on screens.
- PVCARM offers full compliance with DICOM (Digital Imaging and Communications in Medicine) standards to allow the sharing of medical information with other PACS (Picture Archiving and Communication System Server).

VIII. Non clinical testing

Testing was performed successfully according to the following standards:

- EN 60601-1:2006/A1:2013
- EN 60601-1-2:2015 (IEC 60601-1-2: 2014)
- IEC 60601-1-3:2008+A1:2013
- IEC 60601-2-43:2010
- IEC 60601-2-54:2009 + A1::2015

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"
- "Guidance for the Submission of 510(k) for Solid State X-ray Imaging devices"
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff Document Issued on: October 2, 2014

- Pediatric Information for X-ray Imaging Device Premarket Notifications Guidance for Industry and Food and Drug Administration Staff Document issued on November 28, 2017.

All applicable aspects of these guidance documents listed in this 510(k) summary have been addressed.

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 1020.32: Fluoroscopic Equipment

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 FLUSION-9001 Fluoroscopic C-arm Mobile 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 FLUSION-9001 Fluoroscopic C-arm Mobile X-ray System is suitable for its intended use and user instruction of the device.