DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 20, 2016

GEMSS MEDICAL SYSTEMS CO., LTD
% Mr. Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
HOUSTON TX 77025

Re: K160065
Trade/Device Name: KMC-650 GEMSS Medical System Surgical Mobile Fluoroscopic X-ray System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OXO, JAA
Dated: April 13, 2016
Received: April 18, 2016

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160065

Device Name
KMC-650
GEMSS Medical System Surgical Mobile Fluoroscopic X-ray System

Indications for Use *(Describe)*

KMC-650 Surgical Mobile Fluoroscopic X-ray System is indicated for use in generating fluoroscopic / radioscopic images of human anatomy. This device is not intended for interventional guided procedure & mammographic applications.

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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SECTION 07

510(k) SUMMARY

510(k) SUMMARY
For KMC-650

Submitted by:

GEMSS MEDICAL SYSTEMS CO., LTD.
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Contact – Mr. Sangwoo Lee
Internet – http://www.gemss-medical.com

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR Part 807.92.

Date: April 12, 2016

1. General Information:

Establishment:
GEMSS MEDICAL SYSTEMS CO., LTD.
2nd Floor, 29, Dunchon-daero 541 beon-gil, Jungwon-gu, seongnam-si,
KOREA, REPUBLIC OF 13216
Registration Number: 3003384390

GMESS MEDICAL SYSTEMS CO., LTD. is the holder/owner for this 510(k).

2. Official Correspondent Contact:

Dave Kim
Mtech Group
8310 Buffalo Speedway
Houston, TX 77025
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FAX : 713-583-8988

E-mail : davekim@mtech-inc.net

3. Device name and Classification

Trade Name	: KMC-650
Classification Name	: Image-intensified Fluoroscopic Mobile X-ray System
Classification Panel	: Radiology
Classification Regulation	: 21 CFR 892. 1650

Device Classification : Class Ⅱ
Primary product code : OXO
Secondary product code :JAA

4. Legally Marketed Predicated Device

Trade Name : KMC-950
510(k) Clearance # : K032761
Clearance date : 05/14/2004
Classification Name : Image Intensified Fluoroscopic Mobile X-ray System
Classification Panel : Radiology
CFR Section : 21CFR 892.1650
Device Class : Class Ⅱ
Product Code : JAA, OWB, OXO

5. Device Description

The KMC-650 Surgical Mobile Fluoroscopic 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. Not to be used for mammography.

KMC-650 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 the image intensifier. This system can be applied in emergency room, operation room, cast room or etc. of hospital.

6. Indications for Use

KMC-650 Surgical Mobile Fluoroscopic X-ray System is indicated for use in generating fluoroscopic / radioscopic images of human anatomy. This device is not intended for interventional guided procedure & mammographic applications

7. Substantial Equivalence

KMC-650 is substantially equivalent to the commercially available KMC-950 of GEMSS Medical System (K032761). The detailed SE discussion is provided in SECTION 12.

		Predicate device	Proposed device
Model Name		KMC-950	KMC-650
510(k) Number		K032761	
Manufacturer		GEMSS Medical System Co., Ltd	GEMSS Medical System Co., Ltd
X-ray tube	Manufacturer	Varian (RAD-99)	Toshiba (DF-151SBR)
	Anode Type	Rotating	Stationary
	Heat Capacity	300,000 HU	45,000 HU
	Anode Heat Cooling	70kHU/min	47kHU/min
	Focal size	0.3mm / 0.6mm	0.5mm/1.5mm
X-ray generator	Manufacturer	POSKOM (HTC-120)	POSKOM (C-650)
	X-ray Generator Type	High frequency / inverter type	High frequency / inverter type

	Power Output	12.5 kW	2.2 kW
Fluoroscopic Mode	kV range	40 to 125 kV See below discussion for differences	40 to 110 kV See below discussion for differences
	mA range	0.5 to 5 mA. See below discussion for differences	0.5 to 4 mA. See below discussion for differences
	Pulse Fluoro	Yes	Yes
	ABS function	Yes	Yes
	Snap Shot	8.0 mA shot available	8.0 mA shot available
	Boost Shot	20.0 mA shot available	20.0 mA shot available
Image Intensifier	Manufacturer	Thales / Toshiba	Thales / Toshiba
	Size	9″	9″
	Magnification	9″ / 6″ / 4.5″	9″ / 6″ / 4.5″
Camera	Manufacturer	RAYSIS	GEMSS
	Type	½″ CCD	½″ CCD
	Active pixels	512 x 512	1,024 x 1,024
C-arm	Manufacturer	GEMSS medical Systems Co., Ltd	GEMSS medical Systems Co., Ltd
	SID	950mm	1000mm
	Range of C-ram Rail Rotation	115° (90° / 25°)	135° (90° / 45°)
	Range of the Liner FR-arm Movement	200 mm	200 mm
	Range of the Linear T-arm Movement	500 mm	500 mm
	Range of Swing-arm Rotation	± 12.5°	± 12.5°
	Range of Stay-arm Rotation	360°	360°
Image Processing	Storage Capacity	Digital	Digital
	Image Matrix Size	5,000 images	5,000 images
	Monitor Size	17″	19″
Collimator	Model Name	KMC-950CM	KMC-650CMR
	Manufacturer	GEMSS medical Systems Co., Ltd	GEMSS medical Systems Co., Ltd
	Collimator	Motor control / rotation	Motor control / rotation
	Power Requirements	DC 24V	DC 24V

8. Summary of technological characteristics of the device compared to the predicate device

※ Performance Differences in the Generator

Items		KMC-950	KMC-650
Generator	MODEL	HTC-120	C-650
	Max Power	12.5 kW	2.2 kW
Device Specifications	kV	Fluoro : 40 - 125 kV	Fluoro : 40 - 110 kV
	mA	Fluoro : 0.5~ 5 mA	Fluoro : 0.5 - 4 mA,

➔ The generator capacity must be sufficient to meet the fluoroscopy and Radiography exposure requirements. The power requirement for a generator depends on the size, length and thickness of X-ray Tube (Anode) Filament. The generator's mA output also depends on the focal spot sizes.

A typical fluoroscopy mode for KMC-950 and KMC-650 requires the power of 1 kW or less. Therefore, the generator outputs for KMC-650 and KMC-950 in fluoroscopy mode is not significantly different.

KMC-650/950 Firmware Comparison Table

Items	KMC-650	KMC-950	Remarks
Camera Board	650CAMB	950CAMB	Camera specifications are different.(active pixels)
Main Board	650MCB	950MCB	Generator Control, Key Input function operates differently.
OP Control Board	650OPCB	-	A separate OP Board exists for KMC-650 whereas KMC-950 has the main control board only without a separate OP board

KMC-650 is designed as a set of components (X-ray tube and housing, imaging intensifier, collimator, generator). KMC-650 and components conform to the FDA recognized standards. Based on the recognized standard conformity evidences related to electro-, mechanical-, software-, clinical-, and risk management, it is confirmed that the all technological characteristics of KMC-650 is substantially equivalent to the predicate device.

9. General Safety and Effectiveness Concern

To minimize electrical, mechanical, and radiation hazards, GEMSS MEDICAL SYSTEMS CO., LTD. adheres to recognized and established industry practice, and all equipment complies with the relevant FDA and international standards.

Through verification and validation activities, the safety and effectiveness of KMC-650 is verified and validated. Engineering testing and standards compliance testing were successfully conducted and did not raise any new safety questions or concerns or identify new risks. And instructions for use are included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

Electrical, EMC, mechanical, environmental safety and performance testing according to FDA recognized standards were performed. All test results were satisfactory. Applied standards are as follows:

- IEC60601-1:2005
- IEC60601-1-2:2007
- IEC60601-1-3:2008
- IEC60601-2-28:2010
- IEC60601-2-43:2010
- IEC60601-2-54:2009
- NEMA PS 3.1-3.20
- ISO14971:2012

And, EPRC regulation was satisfactory.

- 21CFR1020.32

In addition, FDA guidance were satisfactorily considered.

- Guidance for the Submissions of 510(k)s for Solid State X-ray Imaging Devices

Based on the robust set of results from the non-clinical and clinical studies that have been performed, KMC-650 has been found to be substantially equivalent to the predicate device as well as found to be a safe and effective surgical mobile fluoroscopic X-ray imaging system.

10. Conclusion as to Substantial Equivalence

KMC-650 is substantially equivalent to the predicate device KMC-950 (K032761). These devices are very similar in the intended use, the design principle, the performance and the applicable standards. Some characteristics, for example, their appearance, the user interfaces are different. However the compliance reports, demonstrations and descriptions in this submission STED provide demonstration that these small and minor differences do not raise any new questions of safety and effectiveness. So GEMSS MEDICAL SYSTEMS CO., LTD. concludes KMC-650 is substantially equivalent to the predicate device KMC-950 (K0327618).