DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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GEMSS MEDICAL SYSTEMS CO., LTD. May 26, 2017
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
8310 Buffalo Speedway
Houston, Texas 77025

Re: K163140
Trade/Device Name: SPINEL 12HD Interventional Fluoroscopic 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
Dated: April 25, 2017
Received: April 28, 2017

Dear Dave 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,

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)*
K163140

Device Name
SPINEL 12HD
Interventional Fluoroscopic Mobile X-ray System

Indications for Use *(Describe)*

SPINEL 12HD Surgical Mobile Fluoroscopic 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.

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510(k) SUMMARY

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: May 18, 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

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
TEL : 713-467-2607

FAX : 713-583-8988

E-mail : davekim@mtech-inc.net

3. Device name and Classification

Trade Name	: SPINEL 12HD Interventional Fluoroscopic Mobile X-ray System
Classification Name	: Image Intensified Fluoroscopic X-ray System
Classification Panel	: Radiology
Classification Regulation	: 21 CFR 892. 1650
Device Classification	: Class Ⅱ
Product Code	: OWB, OXO, JAA

4. Legally Marketed Predicated Device

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

5. Reference Device

Trade Name : Artis one Angiographic System
510(k) Clearance # : K133580
Clearance date : 04/28/2014
Classification Name : Image Intensified Fluoroscopic X-ray System
Classification Panel : Radiology
CRF Section : 21CFR 892.1650
Device Class : Class II
Product Code : OWB, JAA, IZI

6. Device Description

The SPINEL 12HD 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. This device is not intended to be used for mammography applications.

SPINEL 12HD 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.

6. Indications for Use

SPINEL 12HD Surgical Mobile Fluoroscopic 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.

7. Substantial Equivalence

SPINEL 12HD 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	SPINEL 12HD
510(k) Number	K032761	
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, 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.	SPINEL 12HD Surgical Mobile Fluoroscopic 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.

		Predicate device KMC-950 (K032761)	Proposed device SPINEL 12HD	Justification
X-ray tube	Manufacturer	Varian (RAD-99)	Toshiba (E7833X)	New X-ray tube was used for the subject device due to the aspect of cost and supply capacity of the manufacturer. Both X-ray tube have equivalent technical specification. There is no difference in the safety and effectiveness for both X-ray tubes. The following risk factors were considered and reviewed※ Hazard ID : RM-12HD-01 / RM-12HD-02 / RM-12HD-03 / RM-12HD-09 / RM-12HD-43 / RM-12HD-44 / RM-12HD-45 / RM-12HD-49 / RM-12HD-50 / RM-12HD-51 / RM-12HD-52 / RM-12HD-53 / RM-12HD-70 / RM-12HD-72 / RM-12HD-74 / RM-12HD-75 IEC60601-1, IEC60601-1-3
	Anode Type	Rotating	Rotating	
	Heat Capacity	300,000 HU	300,000 HU	
	Anode Heat Cooling	70kHU/min	70kHU/min	
	Focal size	0.3mm / 0.6mm	0.3mm / 0.6mm	
X-ray generator	Manufacturer	POSKOM	POSKOM	
	X-ray Generator Type	High frequency / inverter type	High frequency / inverter type	
	Power Output	12 kW	12 kW	
Fluoroscopic Mode	kV range	40 to 125 kV See below discussion for differences	40 to 120 kV See below discussion for differences	Changed X-ray control range to improve output stability and effectiveness compared to the predicate device. kV → Adjusted the kV range to be aligned with the X-ray exposure setting. mA → Adjusted and broadened the mA range for more stable X-ray exams of different human body parts. ※Hazard ID : RM-12HD-01 / RM-12HD-02 / RM-12HD-03 / RM-12HD-43 / RM-12HD-49 / RM-12HD-50 / RM-12HD-51 / RM-12HD-52 / RM-12HD-53 / RM-12HD-70 / RM-12HD-74 / RM-12HD-75
	mA range	0.5 to 5 mA. See below discussion for differences	0.2 to 10 mA. See below discussion for differences	
	Pulse Fluoro	Yes	Yes	
	ABS function	Yes	Yes	
	Snap Shot	8.0 mA shot available	6 mA shot available	
	Boost Shot	20.0 mA shot available	8mA / 20.0 mA shot available	
Detector	Manufacturer	Thales (TH9428HP2) Image Intensifier	Pixium 2630S Flat Panel Detector (cleared under K133580)	The new digital FPD of the subject device has better performance specification compared to the image intensifier of the predicate device in terms of image quality and resolution. The following risk factors have been considered and reviewed. ※Hazard ID : RM-12HD-04 / RM-12HD-16 / RM-12HD-17 / RM-12HD-18 / RM-12HD-19 / RM-12HD-20 / RM-12HD-21 / RM-12HD-22 / RM-12HD-23 / RM-12HD-37 / RM-12HD-54 / RM-12HD-64 / RM-12HD-65 / RM-12HD-71 / RM-12HD-73
	Size	9″	11.3 x 10.3 "	
	Magnification	9″ / 6″ / 4.5″	10 ″ / 9″ / 7-7/8″ / 4.5″ (square)	
	DQE	65	70 (@ 0 lp/mm)	
	MTF	92 (@ 2 lp/cm)	59 (@ 1 lp/mm)	
	Central resolution	48 μm	92 μm (184 μm in 2x2 binning)	
	Pixel size		1800 (h) x 1500 (v)	

Camera	Manufacturer	RAYSIS	N/A	N/A
	Type	½" CCD	N/A	
	Active pixels	512 x 512	N/A	
C-arm	Manufacturer	GEMSS medical Systems Co., Ltd	GEMSS medical Systems Co., Ltd	The range of C-arm movement has been broadened to result the coverage of larger region of interest during a patient exam. The following risk factors have been considered an reviewed. ※Hazard ID : RM-12HD-10 / RM-12HD-25 / RM-12HD-28 / RM-12HD-29 / RM-12HD-30 / RM-12HD-32 / RM-12HD-33 / RM-12HD-34 / RM-12HD-35 / RM-12HD-36 / RM-12HD-37 / RM-12HD-38 / RM-12HD-39 / RM-12HD-40 / RM-12HD-41 / RM-12HD-42 / RM-12HD-56 / RM-12HD-57 / RM-12HD-58 / RM-12HD-67 / RM-12HD-68 / RM-12HD-69
	SID	950mm	1000mm	
	Range of C-ram Rail Rotation	115° (90° / 25°)	165° (120° / 45°)	
	Range of the Liner FR-arm Movement	200 mm	220 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°	225°	
Image Processing	Storage Capacity	Digital	Digital	The monitor size has increased to provide better image viewing experience for the user. ※Hazard ID : RM-12HD-04 / RM-12HD-65
	Image Matrix Size	5,000 images	5,000 images	
	Monitor Size	17"	19"	
Collimator	Model Name	KMC-950CM	SPINEL 12HDCMR	

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

The indications for use, operating principle, technical specifications such as X-ray tube head and generator as well as safety characteristics of SPINEL 12HD are identical to those of the predicate device. SPINEL 12HD 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). Based on the recognized standard conformity evidences related to electro-, mechanical-, software-, and risk management, GEMSS Medical System certifies that technological characteristics of SPINEL 12HD are substantially equivalent to KMC-950, the predicate device. SPINEL 12HD 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.).

Even though the hardware specification of X-ray generator is the same, the operating ranges of kV and mA setting of SPINEL 12HD are different compared to KMC-950 to improve the effectiveness of the fluoroscopic exam of different human body type.

- ➔ The X-ray Generator for the subject and predicate device have the identical specification. The dose difference is small under the same irradiation conditions.
- ➔ The SID and the location of ISO center is different for the subject device compared to the predicate device which results a difference in the dose measurement. The measurement was done 150mm away from the ISO center toward the tube.
- ➔ The measurement distance from the X-ray tube for SPINEL 12HD is longer than the distance between the measurement position of the tube of the KMC-950 resulting the dose of SPINEL 12HD slightly lower overall.

The viewing software of the subject device is an updated version of CXV viewing software also used for the predicate device. The subject device is equipped with a digital flat panel detector with higher DQE and MTF performance characteristics compared to the predicate device. The pixel size (1800x1500) of the subject device is better than the active pixel (512x512) of the predicate device. The safety and effectiveness of Pixium 2630S flat panel detector equipped for SPINEL 12HD has been reviewed and cleared by FDA under 510k No: K133580.

The V&V Report for Intelligent object dose control (IODC) and Metal Detected Control (MDC) for SPINEL 12HD contains the software quality and performance testing activities.
The Intelligent Object Dose Control (IODC) is a function to adjust the intensity of the X-ray using the detected object, and the brightness of the desired image can be obtained by optimizing the function of ABC (Auto Brightness Control) according to the distribution of the detected object.
With metal detected control, the brightness of the image is adjusted by distinguishing the attributes of the human body and the attributes of the metal, and reflecting only the attributes of the human body except for the metal part
Both IODC and MDC function are added to optimize (Check the type and position of the object and perform fast process speed and accurate processing.) the ABC function which is already included in the predicate.

The report also contains the device hazard analysis related to IODC and MDC. The images of before and after applying each function have been compared which validates the efficacy of both IODC and MC functions.

The differences between the subject and predicate device do not introduce any new safety or effectiveness concerns for SPINEL 12HD and the sponsor concludes that SPINEL 12HD is substantially equivalent with KMC-950, the predicated device.

9. General Safety and Effectiveness Concern

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

Electrical, EMC, mechanical, environmental safety and performance testing according to FDA recognized standards were performed as verification and validation activities to verify the safety and effectiveness of SPINEL 12HD. Engineering testing and standards compliance testing were successfully conducted and did not raise any new safety questions or concerns or identify new risks. The instruction for use is included within the device labeling, and the information provided will enable the user to operate the device in a safe and effective manner.

. All test results were satisfactory. Applied standards are as follows:

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

The subject device meets EPRC regulation requirements.
- 21CFR1020.30
- 21CFR1020.32

FDA guidance documents:
- FDA guidance for SSXI devices,
- FDA guidance for the Content of Premarket Submissions for Software Contained in Medical Devices

Based on the robust set of results from the non-clinical and clinical studies that have been performed, SPINEL 12HD 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

SPINEL 12HD is substantially equivalent to the predicate device KMC-950 (K032761). These two devices are same or very similar in the intended use, the design principle, the performance and the applicable standards. Some characteristics, for example, capacity of X-ray tube housing and generators, X-ray imager as well as user interfaces are different. However, the compliance reports and descriptions in this submission STED provide demonstration that these differences do not raise any new questions of safety and effectiveness. Therefore, it is the sponsor's opinion that SPINEL 12HD is substantially equivalent with the predicate device KMC-950 (K0327618).