DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 13, 2016

SG HealthCare Co., Ltd.
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K150816
Trade/Device Name: Jumong Series Stationary Radiographic System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR, MQB
Dated: March 20, 2015
Received: March 27, 2015

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of May 8, 2015

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 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″ (21CFR 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)*
K150816

Device Name
Jumong Series Stationary Radiographic Systems

Indications for Use *(Describe)*

The Jumong Series Stationary Radiographic System is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest. abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.

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, 510(k) K150816

Submitter: SG Healthcare Co., Ltd.
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Contact: YOSEP PARK, sales@sghealthcare.com
Date Prepared: April 11, 2015

1. **Identification of the Device:**
   Proprietary-Trade Name: **Jumong Series Stationary Radiographic System**
   Classification Name: Stationary X-Ray System, Product codes KPR and MQB
   Common/Usual Name: Diagnositc X-Ray System
   Device Class: II per regulation 21CFR 892.1680

2. **Equivalent legally marketed device: K133782, Sedecal Nova FA DR System, Sedecal SA.**

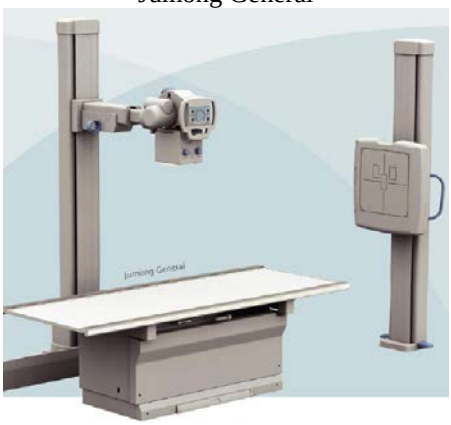
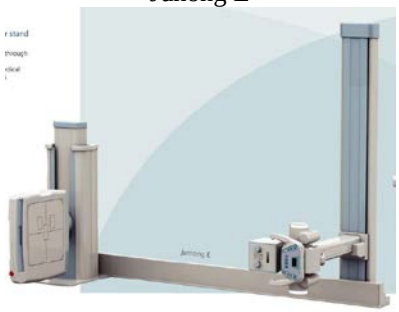
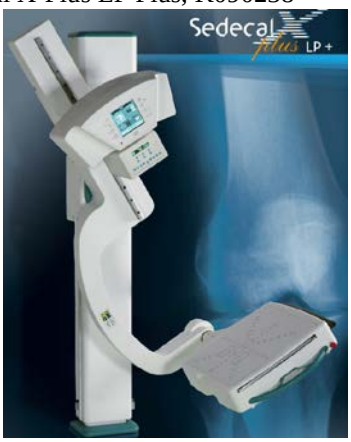
3. **Indications for Use** The Jumong Series is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest. abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.

4. Description of the Device: This device represents a new combination of an already cleared solid state digital x-ray acquisition panel with software and diagnostic x-ray compnents required to make a complete system. Film cassettes may be employed in place of the digital panel. The purchaser can select from one of four configurations. Please see the photos below. The x-ray generator is a CPI CMP 200DR. The x-ray tubes are supplied by Varian (RAD-14), and the collimator is the Ralco R225 ACS DHHS. The system complies with the CDRH Radiological Health performance standard in the Code of Federal Regulations, as well as the voluntary IEC standards IEC 60601-1 and IEC 60601-1-2. All major components are either UL or CSA listed.

5. **Safety and Effectiveness, comparison to predicate device**. This combination device has the same indications for use and very similar technological characteristics as the predicate device, and employs already 510(k) cleared digital panels and software.

6. **Substantial Equivalence Chart: Please see the next page.**

Characteristic	Sedecal Nova FA K133782	SG Healthcare, Co. Ltd., Jumong Series Stationary Radiographic System
Intended Use:	Sedlecal "NOVA FA DR System" is intended for use by a qualified, trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest. abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.	Jumong Series is intended for use by a qualified, trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest. abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. Not for mammography.
Configuration of Digital Panels	Battery or AC operated wireless IEEE 802.11n or Wired Ethernet	SAME
Digital Panel Models and their clearance numbers	CXDI Canon Detector 401C/401C Compact (K103591) CXDI Canon Detector 55C (K091436) CXDI Canon Detector 501C (K111682)	Vieworks K122865 Vivix-S Wireless K122866 Vivix-S With Vxvue K120020 Vivix-S
Image acquisition panel specifications	3,320 x 3,408 125 μm (401C) or 2,208 x 2,688 pixels 160 μm (55C) 2,800 x 3,408 Pixels 125 μm (501C)	FXRD-1717SA, FXRD-1717SB) 3,072 x 3,072, 140μm or FXRD-1417SA, FXRD-1417SB) 2560 x 3072, 140μm Wireless: FXRD-1417WA, FXRD-1417WB, 2560 x 3072, 140μm
DICOM	DICOM 3	DICOM 3
WiFi Wireless IEEE802.11n (All others are Ethernet Tethered.)	Not applicable, but compatible with all Canon panels, including wireless.	K122865 Vivix-S Wireless
Image acquisition software	CANON cleared in K111682	Vieworks as cleared in K122866 Vivix-S With Vxvue
Power Source	AC Line, various voltages available	SAME

Characteristic	Sedecal Nova FA K133782	SG Healthcare, Co. Ltd., Jumong Series Stationary Radiographic System
Photos		Jumong M  Jumong General  Junong E 
Alternate configuration	Sedecal X-Plus LP Plus, K090238 	Jumong U 
Generator	Sedecal SHF	CPI CMP 200DR
Collimator	Ralco R225	Ralco R225

Characteristic	Sedecal Nova FA K133782	SG Healthcare, Co. Ltd., Jumong Series Stationary Radiographic System
Performance Standard	FDA 21CFR1020.30-31	SAME
Electrical safety	Electrical Safety per IEC-60601. UL listed	SAME

7. Summary of non-clinical testing: We performed integration testing. The results of a review of bench, safety test, and software validation documentation indicates that the new device is as safe and effective as the predicate device. The device conforms to US Performance Standards. The device conforms to this list of voluntary standards:

Standards No.	Standards Organization	Standards Title	Version	Date
60601-1	IEC	Safety of Electrical Medical Equipment	2005 + A1 (2012)	2005 + A1 (2012)
60601-1-2	IEC	Electromagnetic Compatibility	2007	2007
60601-1-3:	IEC	Collateral Standard Radiation protection in diagnostic X ray equipment	2008	2008
60601-1-6	IEC	Collateral standard: Usability	2010 3ed. +A1:2013	2010-2013
60601-2-28	IEC	Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	2010, 2ed	2010
60601-2-54	IEC	Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	2009 1ed	2009
62366	IEC	Application of usability engineering to medical devices	2007-1ed	2007
PS 3.1 - 3.18 (2009	NEMA	Digital Imaging and Communications in Medicine (DICOM) Set (This applies to the Digital Panel)	3	2009

8. Summary of clinical testing: Clinical images were provided; these images were not necessary to establish substantial equivalence based on the modifications to the device (e.g., use of previously cleared detectors) but they provide further evidence in addition to the laboratory performance data to show that the complete system works as intended.

9. Conclusion: After analyzing software integration validation, safety testing data, and clinical images, it is the conclusion of SG Healthcare that the "Jumong Series" is as safe and effective as the predicate device, has few technological differences, and has identical indications for use, thus rendering it substantially equivalent to the predicate device.