February 23, 2023

SG Healthcare CO LTD
% Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES, FL 34114

Re: K230241
Trade/Device Name: Jumong General
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary X-Ray System
Regulatory Class: Class II
Product Code: KPR, MQB
Dated: January 30, 2023
Received: January 30, 2023

Dear Mr. Daniel Kamm:

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,

Lu Jiang

Lu Jiang, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of Radiological Imaging Devices and Electronic Products
OHT8: Office of 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)*
K230241

Device Name
Jumong General

Indications for Use *(Describe)*
The Jumong General 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) K230241

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Contact: YOSEP PARK, sales@sghealthcare.com
Date Prepared: February 1, 2023

1. **Identification of the Device:**
   System.Trade/Device Name: Jumong General
   Regulation Number: 21 CFR 892.1680
   Regulation Name: Stationary x-ray system
   Regulatory Class: II
   Product Code: KPR, MQB

2. **Equivalent legally marketed device: K150816,**
   System.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.

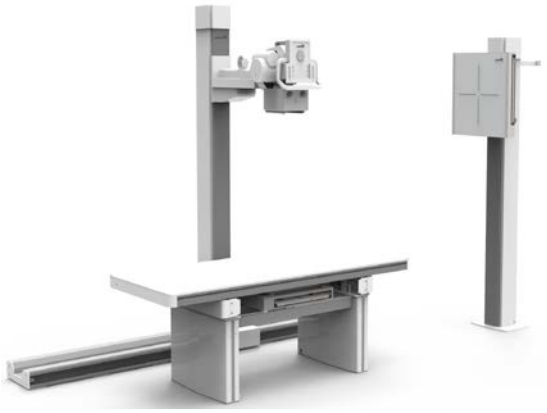
3. **Indications for Use** The Jumong General is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest. abdomen, extremities, and other body parts. Applications can be performed 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 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 x-ray generator has been changed to a Delta Electronics Delta DMP 100R The collimator has been changed to a Fairy Medical Electronics model CRUX FR04. The tubehead has been changed to a Hangzhou Kailong Medical Instruments Co., Ltd H1074X. 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.

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	K150816, Jumong Series Stationary Radiographic System SG Healthcare, Co. Ltd.,	Modified: Jumong General
Intended Use:	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.	Jumong General 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. UNCHANGED
Generator	CPI CMP 200 DR kVp range: 40 to 150 kVp, depending on model	Delta Electronics DMP 100R kVp range: 40 to 150 kVp SAME
Collimator	Ralco Model R225	Fairy Medical Electronics CRUX FR04
Tubehead	Varian RAD14	Hangzhou Kailong Medical Instruments Co., Ltd H1074X
Digital Panel Models and their clearance numbers	Vieworks K122865 Vivix-S Wireless K122866 Vivix-S With Vxvue K120020 Vivix-S	SAME
Image acquisition panel specifications	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	SAME
DICOM	DICOM 3	SAME
Image acquisition software	Vieworks as cleared in K122866 Vivix-S With Vxvue	SAME
Power Source	AC Line, various voltages available	SAME

Characteristic	K150816, Jumong Series Stationary Radiographic System SG Healthcare, Co. Ltd.,	Modified: Jumong General
Photo, floor mount		
Photo, ceiling mount		
Performance Standard	US Radiation Safety Performance Standard	SAME
Electrical safety/EMC Standards compliance	IEC 60601-1, IEC 60601-1-2	SAME

7. **Summary of non-clinical testing**: We performed integration and image quality testing. The device conforms to the US Performance Standard. The new generator was tested by an NRTL to comply with: IEC 60601-2-54:2009+A1+A2, IEC 60601-1:2005+Corrigendum 1+Corrigendum 2+A1, IEC 60601-1-3:2008+A1, and IEC 60601-1-6:2010+A1. EMC testing complies with IEC 60601-1-2:2014.
   The new collimator was tested for compliance with EN/IEC 60601-2-54 for radiation leakage.
   The new tubehead was tested to IEC 60613:2010 Electrical and loading characteristics of X-ray tube assemblies for medical diagnosis and IEC 60336:2005 Medical electrical equipment - X-ray tube assemblies for medical diagnosis - Focal spot dimensions and related characteristics.
   Test images were acquired which showed excellent diagnostic quality. Note that the digital x-ray receptor panels and software have not changed from the predicate.
   Every unit is tested for electrical safety, input power, display of operation and exposure factors, collimator operation, reproducibility, and accuracy. A risk analysis was performed with regard to the

modifications. No software modifications were made to the imaging chain.

8. **Summary of clinical testing**: Not applicable.

9. **Conclusion:** 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. After analyzing safety testing data, final checkout, and test images, it is the conclusion of SG Healthcare that the modified "Jumong General" 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.