October 6, 2022

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

Re: K222080
Trade/Device Name: Garion
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB
Dated: July 8, 2022
Received: July 15, 2022

Dear 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 and Part 809); 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,

Laurel Burk, Ph.D.
Assistant Director
Diagnostic X-Ray Systems Team
DHT8B: Division of 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)*
K222080

Device Name
Garion

Indications for Use *(Describe)*
The Garion is intended to be used and operated by: adequately trained, qualified and authorized health care professionals who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device. The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients, except neonates (birth to one month), within the limits of the device. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of 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, 510(k) K222080

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Contact: Byungju Kang, bjkang@sghealthcare.com
Date Prepared: September 14, 2022

1. Identification of the Device:
Trade/Device Name: Garion
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: II
Product Code: OWB

2. Equivalent legally marketed device: K183040, Philips Medical Systems International B.V.
Trade/Device Name: Zenition 70
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB

3. Reference Device:
The digital x-ray image acquisition panel employed has been cleared for the same intended use within: K200218
Trade/Device Name: Digiscan FDX
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: OWB, JAA, OXO

4. Indications for Use
The Garion is intended to be used and operated by: adequately trained, qualified and authorized health care professionals who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device. The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients, except neonates (birth to one month), within the limits of the device. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.

5. Description of the Device:
GARION is mobile fluoroscopy system is designed to provdie fluoroscopic and spot-film images of thepatient during diagnostic, surgical procedures.
This device is a digital X-ray radiographic equipment that consists of high voltage generator, X-ray control unit, X-ray tube unit, Collimator, image processing unit. The image processing unit consists of medical image detector, power supply, medical image collecting unit and relevant software.

• Fine-Tuned Movement
• 5kW FPD Surgical C-arm
• Garion is equipped with a high resolution FPD. Its composition, along with othe components such as positive/negative inversion, realtime zoom & rotation,as well as advanced noise reduction and optimized contrast/brightness, providing clear and enhanced image quality.
• Attachable Grid
The Grid can be attached and detached, allowing low-dose examination for each part.
• Dual Laser Pointer
Using the dual laser pointer, it is possible to set the patient's position without unnecessary exposure.
• Powerful Digital lmage, Processing and Display
The combination of Dynamic FPD means that Garion provides a excellent quality on screen image. Our advanced image-processing technology enables you to utilize various functions such as image flip (horizontal & vertical), image rotation (360˚), realtime zoom, noise reduction, and realtime edge enhancement, etc.

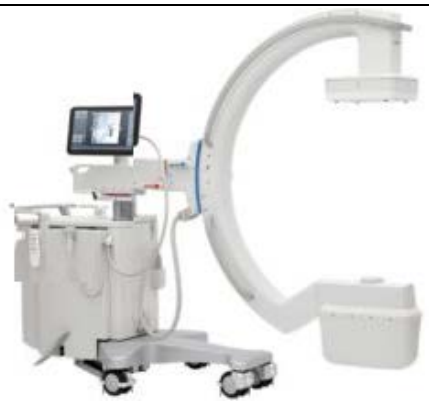
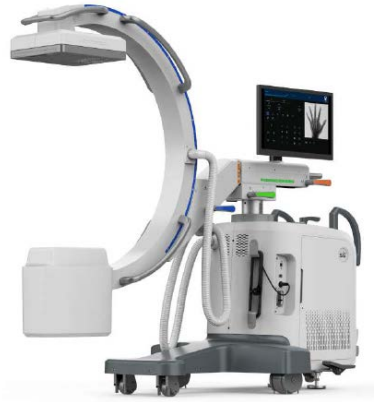
6. Safety and Effectiveness, comparison to predicate device. This device has the same indications for use and very similar technological characteristics as the predicate device. This can be readily seen in the comparison table presented below. Many of the characteristics compared are the same, while other differences are insignificant in nature. The digital receptor panel chosen has already been cleared (reference device) for the same intended use.

7. Comparison Table with the Predicate Device for technological characteristics:

Detailed comparison chart

		Predicate device Zenition 70 K183040	**Proposed device Garion**	SE
Indications for Use		The Zenition 70 device is intended to be used and operated by: adequately trained, qualified and authorized health care professionals who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device. The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients, except neonates (birth to one month), within the limits of the device. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.	The Garion is intended to be used and operated by: adequately trained, qualified and authorized health care professionals who have full understanding of the safety information and emergency procedures as well as the capabilities and functions of the device. The device is used for radiological guidance and visualization during diagnostic, interventional and surgical procedures on all patients, except neonates (birth to one month), within the limits of the device. The device is to be used in health care facilities both inside and outside the operating room, sterile as well as non-sterile environment in a variety of procedures.	SAME
X-ray Tube	Anode Type	Rotating Anode	Rotating Anode	SAME
	Anode target angle	10°	10°	SAME
	Focal size	0.3/0.6	0.3/0.6	SAME
Fluoro-scopic Mode	kV range	40-120 kV	40-125 kV	Similar. Slightly higher

		Predicate device Zenition 70 K183040	Proposed device Garion	SE
				peak kVp
	mA range	0.5-60 mA	0.1-100 mA	Similar, slightly higher mA
	Pulse Fluoro	YES	YES	SAME
	ABS function	YES	YES	SAME
FPD Image Detect-or	Make	Trixell's PX2121S	IRAY 's, Mercu 0909F	--
	Model	8.15" x 8.15"	9" x 9"	Similar, slightly larger image.
	Scintilla-tor	Cesium Iodide	Cesium Iodide	SAME
	Detector type	amorphous silicon detector	amorphous silicon detector	SAME
	Active detector size	207×207 mm	228.6 mm x228.6 mm	Similar, slightly larger image
	Total pixel matrix	1344 x 1344	1024×1024	Similar
	Pixel pitch	154 µm	205 µm	Similar
	A/D Convers-ion	16 bit	16 bit	SAME
	MTF (1.0 lp/mm)	0.59	0.64	Similar, slightly better.
	DQE (0 lp/mm)	0.77	0.77	SAME
C-arm	Manu-facturer	Philips	SG HealthCare Co. Ltd.	--
	SID	993mm	980mm	Similar
	Range of C-arm Rail Rotation	±200°	±180°	Similar
	Range of the Linear FR-arm Move-ment	200 mm	200mm	SAME
	Range of the Liner T-arm Move-ment	490 mm	400m	Similar

		Predicate device Zenition 70 K183040	Proposed device Garion	SE
	Range of swing-arm Rotation	± 10°	±15	Similar, slightly better.
Collimator		Motor control / rotation	Motor control / rotation	SAME
Photo				Similar

8. Summary of non-clinical testing: We employed applicable IEC standards:

IEC60601-1, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC60601-1-2, Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC60601-1-3, Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
IEC60601-1-6, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance –Collateral Standard: Usability
IEC60601-2-28 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis
IEC60601-2-54 Medical electrical equipment Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
IEC62366 Medical device – Application of usability engineering to medical devices

In addition, the device complies with the *FDA Radiation Safety Performance Standard Performance Standard for Diagnostic X-Ray Systems and Their Major Components (21CFR 1020.30, 1020.31, 1020.32, 1020.33); Small Entity Compliance Guide.* In addition, labeling was developed and information provided in accordance with this FDA Guidance Document: *Pediatric Information for X-ray Imaging Device Premarket Notifications, Guidance for Industry and Food and Drug Administration Staff.* Labeling also includes reference to the Image Gently website (http://www.imagegently.org/). Also we observed the recommendations contained in the FDA Guidance Document: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices Guidance for Industry and Food and Drug Administration Staff*

9. Summary of clinical testing: Not required for a finding of substantial equivalene..

10. Conclusion: After analyzing bench tests, and safety testing data, SG Healthcare concludes that the "Garion" is as safe and effective as the predicate device "Zenition 70" has few technological differences and has identical indications for use, thus rendering it substantially equivalent to the predicate device.