Shimadzu Corporation
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Ct.
NAPLES FL 34114

March 15, 2019

Re: K190373
Trade/Device Name: SONIALVISION G4
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA
Dated: January 27, 2019
Received: February 19, 2019

Dear Mr. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia Mills, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K190373

Device Name
SONIALVISION G4

Indications for Use *(Describe)*

The equipment is intended to be used for the fluoroscopy/radiography diagnosis in hospital.
The equipment must only be operated by qualified personnel, such as radiography technicians or those with equivalent qualifications.
The equipment is used for total patient population.
The equipment is NOT intended to be used for Mammography screening.
The equipment is NOT intended to be used for interventional procedure.
The equipment is used for radiographic, fluoroscopic, angiographic and pediatric examinations.
Stored images in the equipment can be used for re-monitoring, image processing, storing to optical media (CD/DVD), and sending to DICOM server.
The Tomosynthesis option for the SONIALVISION G4 is intended to generate tomographic images of human anatomy including chest or extremities. Tomosynthesis technique is used to produce a specific cross-sectional plane of the body by reconstruction of tomographic acquisition. The device is not intended for 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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510(k) Summary: 510(k) Number K190373

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Date Prepared: March 4, 2019

Contact: Toshio Kadowaki; Phone: +81-75-823-1920
E-mail: kadowaki@shimadzu.co.jp

1. **Identification of the Device:**
   Trade/Device Names: SONIALVISION G4
   Regulation Number: 21CFR892.1650
   Regulation Name: Image-intensified fluoroscopic x-ray system
   Regulatory Class: II
   Product Code: JAA
   Common/Usual Name: fluoroscopic x-ray system

2. **Equivalent legally marketed device: K142341**
   Trade/Device Name: SONIALVISION G4
   Manufacturer: Shimadzu.
   Regulation Number: 21CFR892.1650
   Regulation Name: Image-intensified fluoroscopic x-ray system
   Regulatory Class: II
   Product Code: JAA
   Common/Usual Name: fluoroscopic x-ray system

3. **Reference device (new digital panel employed: K171194)**
   Trade/Device Name: AS-10, CXDI-401RF
   Regulation Number: 21 CFR 892.1650
   Regulation Name: Image-intensified fluoroscopic x-ray system
   Regulatory Class: Class II
   Product Code: OWB, JAA, MQB

4. **Indications for Use (intended use): The equipment is intended to be used for the fluoroscopy/radiography diagnosis in hospital. The equipment must only be operated by qualified personnel, such as radiography technicians or those with equivalent qualifications. The equipment is used for total patient population. The equipment is NOT intended to be used for Mammography screening. The equipment is NOT intended to be used for interventional procedure. The equipment is used for radiographic, fluoroscopic, angiographic and pediatric examinations. Stored images in the equipment can be used for re-monitoring, image processing, storing to optical media (CD/DVD), and sending to DICOM server. The Tomosynthesis option for the SONIALVISION G4 is intended to generate tomographic images of human anatomy including chest or extremities. Tomosynthesis technique is used to produce a specific cross-sectional plane of the body by reconstruction of tomographic acquisition. The device is not intended for mammographic applications.**

5. **Description of the Device: The Shimadzu SONIALVISION G4 is a universal X-ray RF system offering radiographic, fluoroscopic, angiographic and tomosynthesis techniques. Tomosynthesis technique is enabled by additional software option to the digital radiography system of the SONIALVISION G4.**

The Shimadzu SONIALVISION G4 is floor mounted table, and the system can be configured with Digital Radiography System, X-ray High Voltage Generator, Collimator and X-ray Tube. The purpose of this submission is to introduce an additional compatible digital x-ray receptor panel. This panel is manufactured by Canon. The panel was cleared by FDA for fluoroscopic use in K171194.

6. **Safety and Effectiveness, comparison to predicate device. The results of bench testing indicates that the new device is as safe and effective as the predicate device. Proper system operation is fully verified upon installation.**

7. **Substantial Equivalence Chart: Below.**

	K142341, SONIALVISION G4	**MODIFIED SONIALVISION G4**
Indications for Use:	The equipment is intended to be used for the fluoroscopy/radiography diagnosis in hospital. The equipment must only be operated by qualified personnel, such as radiography technicians or those with equivalent qualifications. The equipment is used for total patient population. The equipment is NOT intended to be used for Mammography screening. The equipment is NOT intended to be used for interventional procedure. The equipment is used for radiographic, fluoroscopic, angiographic and pediatric examinations. Stored images in the equipment can be used for re-monitoring, image processing, storing to optical media (CD/DVD), and sending to DICOM server. The Tomosynthesis option for the SONIALVISION G4 is intended to generate tomographic images of human anatomy including chest or extremities. Tomosynthesis technique is used to produce a specific cross-sectional plane of the body by reconstruction of tomographic acquisition. The device is not intended for mammographic applications	The equipment is intended to be used for the fluoroscopy/radiography diagnosis in hospital. The equipment must only be operated by qualified personnel, such as radiography technicians or those with equivalent qualifications. The equipment is used for total patient population. The equipment is NOT intended to be used for Mammography screening. The equipment is NOT intended to be used for interventional procedure. The equipment is used for radiographic, fluoroscopic, angiographic and pediatric examinations. Stored images in the equipment can be used for re-monitoring, image processing, storing to optical media (CD/DVD), and sending to DICOM server. The Tomosynthesis option for the SONIALVISION G4 is intended to generate tomographic images of human anatomy including chest or extremities. Tomosynthesis technique is used to produce a specific cross-sectional plane of the body by reconstruction of tomographic acquisition. The device is not intended for mammographic applications **EXACTLY THE SAME**
Note: All technical characteristics for the predicate and the modified system are IDENTICAL except for the digital receptor panels, which are compared below.		
Manufacturer	Varian Medical Systems	Varian Medical Systems **OR** Canon Medical Equipment Group
Model	PaxScan™ 4343CB, our model number SDF-1717AF	PaxScan™ 4343CB, our model number SDF-1717AF **OR:** Canon AS-10, CXDI-401RF (K171194) our model number SFD-1717BF
Size	43 x 43 CM	SAME
Pixel Size	139µm	160 µm
Number of Pixels	3072 x 3072	2,688 x 2,688
Acquisition Modes (Binning)	Up to 3 fps (1x1) Up to 15 fps (1x1 or 2x2) Up to 30 fps (2x2)	Up to 3 fps (1x1) Up to 15 fps (1x1) Up to 30 fps (2x2) Equivalent performance
DQE @ 1 µGy in 0 lp/mm, RQA5	0.70	0.75 Slightly better

	K142341, SONIALVISION G4	MODIFIED SONIALVISION G4
Spatial Resolution [MTF@2cycle/mm, RQA5]	0.28	0.28 Same performance
A/D Conversion	16 Bit	16 Bit
Photo of Panel (the modified part)		Added Compatible Panel 

8. **Summary of non-clinical testing: The additional digital receptor panel was subjected to non-clinical testing by its manufacturer, Canon. See K171194 at: https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171194.pdf Our own testing consisted of integration testing, taking and evaluation of test images (both moving and still) and risk analysis oriented to the risks of making the panel manufacturer change. The Users Manual was updated, and supplements were added for Pediatric Imaging (FDA Guidance: *Pediatric Information for X-ray Imaging Device Premarket Notifications*) and for Cybersecurity (FDA Guidance: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.*)**

9. **Summary of clinical testing: Not applicable. Clinical testing was not deemed to be required to show substantial equivalence. We relied on non-clinical testing and compliance with standards.**

10. **Conclusion: After analyzing bench tests, it is the conclusion of Shimadzu Corporation that the MODIFIED SONIALVISION G4 is as safe and effective as the predicate device, has few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.**