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

August 5, 2019

Re: K191877
Trade/Device Name: FLUOROspeed
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: Class II
Product Code: JAA
Dated: July 1, 2019
Received: July 15, 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/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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191877

Device Name

FLUOROspeed

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.

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 K191877

Shimadzu Corporation
1, Nishinokyo-Kuwabaracho, Nakagyo-ku, Kyoto, 604-8511, Japan
Registration Number: 8030233
Phone : +81-75-823-1305 Fax : +81-75-823-1377
Date Prepared: July 26, 2019
Contact: Toshio Kadowaki; Phone: +81-75-823-1920
E-mail: kadowaki@shimadzu.co.jp

1. **Identification of the Device:**
   Trade/Device Names: FLUOROspeed
   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: K190373**
   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
   REFERENCE/SIMILARLY CONFIGURED DEVICES: K173639 (Siemens) and K081091 (GE)
   Trade/Device Names: Luminos (Siemens), Precision (GE)
   Manufacturers: Siemens and GE.
   Regulation Numbers: 21CFR892.1650
   Regulation Name: Image-intensified fluoroscopic x-ray system
   Regulatory Class: II
   Product Code: OWB (Siemens) JAA (GE)
   Common/Usual Name: Fluoroscopic x-ray system

3. **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.

4. **Description of the Device:** The Shimadzu FLUOROspeed is a universal X-ray RF system offering radiographic, fluoroscopic, and angiographic modes. As compared to our recently cleared system the SONIALVISION G4, (K190373) the positions of the tube head and the digital x-ray receptor panel have

been swapped. This was done to respond to customer demand. This configuration is identical to products offered by Siemens (K173639) and GE Healthcare (K081091). The FLUOROspeed is intended to be used as a universal diagnostic imaging system for radiographic and fluoroscopic studies. Using a flat panel detector, it can perform a range of applications including general R/F, angiography and pediatric examinations. FLUOROspeed may be used for emergency treatment on an outpatient basis, as well as for bedside examinations.

Features:

• A large-field 17-inch FPD and digital image processing enable you to acquire high quality diagnostic images. A second FPD can be added as an option. This is the wireless AeroDR SYSTEM 2 1417HQ cleared by FDA in K151465.

• The equipment employs a high-frequency inverter system with maximum frequency of 50 kHz for high-voltage generation and ensures high efficiency by low-ripple output.

• The X-ray diagnostic table holds a wide examination area and allows radiography from head to foot without the need to move the patient.

• The tabletop can be raised or lowered in the height range from 65 cm to 110 cm to help the patient get on or off and allow the operator to take an unforced pose according to required examinations.

• The operator can assist the patient while operating the X-ray diagnostic table on its front control panel.

• The control panel is equipped with a 10.4-inch LCD touch panel, where the operator can view the patient information or change the fluoroscopy or radiography condition. The screen layout or display options can be switched as appropriate according to the purpose of examination. Customizable hard switches help you access to the frequently used functions with a single touch of a button.

• Low-dose exposure and high image quality are achieved at the same time by incorporating automatic selection of BH-filter (X-ray filter), wave-tail cut-off mechanism for pulsed fluoroscopy, detachable anti-scatter grid, virtual collimation, and single-mask collimator (option).

• A series of radiography conditions for examination can be registered in a program to repeat the same series of radiography.

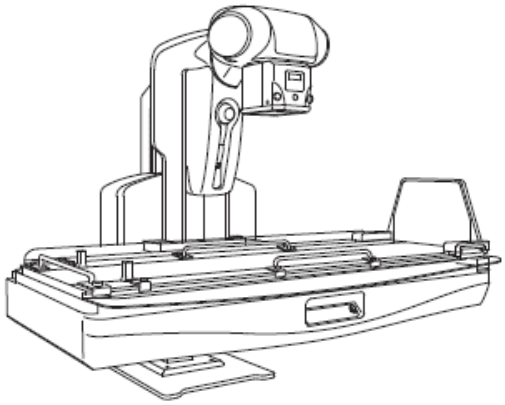
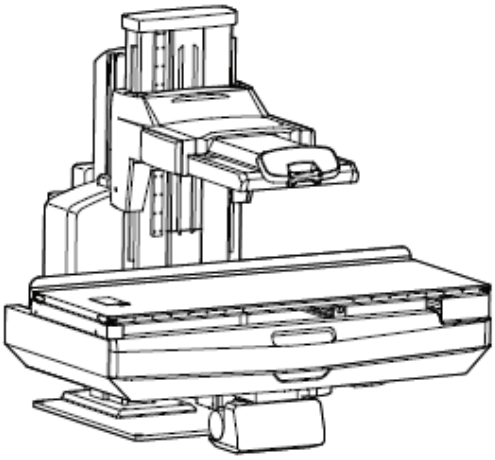
• Image data can be stored for a prolonged period by saving it on DVD-R or CD-R disks in DICOM format.

• The equipment supports DICOM3.0 and allows smooth connection to a hospital network. DICOM Print, Media Storage, DICOM Storage, MWM/MPPS (option) and RDSR (option) are also supported

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and standards testing indicates that the new device is as safe and effective as the predicate device. Proper system operation is fully verified upon installation. Most of the components employed are identical to the predicate device.

6. **Substantial Equivalence Chart: Below.**

	SONIALVISION G4 K190373	FLUOROspeed
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 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 SAME EXCEPT: No Tomosynthesis. Tomosynthesis is not possible because of the fixed position of the tubehead.**
Position of the X-ray tube head	On top, aimed down at the patient resting on the table	Underneath the table aimed up through the table
Position of the digital x-ray receptor panel	In a slot in the table	Overhead where the tubehead used to be.
Digital X-Ray Receptor Panel (Previously Cleared in K171194)		
Manufacturer	Canon Medical Equipment Group	SAME
Model	Canon AS-10, CXDI-401RF (K171194) We call it the SFD-1717BF	SAME
Size	43 x 43 CM	SAME
Pixel Size	160 μm	SAME
Number of Pixels	2,688 x 2,688	SAME
Acquisition Modes (Binning)	Up to 3 fps (1x1) Up to 15 fps (1x1) Up to 30 fps (2x2)	SAME
DQE @ 1 μGy in 0 lp/mm, RQA5	0.75	SAME
Spatial Resolution [MTF@2cycle/mm, RQA5]	0.28	SAME
A/D Conversion	16 Bit	SAME
Digital Radiography Unit	DR-300	SAME

	SONIALVISION G4 K190373	FLUOROspeed
Rad/Fluoro Characteristics		
General Appearance		
Generator	80 kW	80 kW SAME
Collimator	Type R-300	SAME
Ceiling Tube Support	CH-200	SAME
Radiography (Unchanged from Predicate)		
Tube Voltage	40 to 150 kV	40 to 150 kV SAME
Tube Current	10 to 800 mA	10 to 800 mA SAME
mAs	0.5 to 800 mAs	0.5 to 800 mAs SAME
Time	0.001 to 10 sec	0.001 to 10 sec SAME
Fluoroscopy (Unchanged from Predicate)		
Tube Voltage	50 to 125 kV	50 to 125 kV SAME
Tube Current	Max. 20 mA	Max. 20 mA SAME
Time	Total time display: 99 min 59 sec., continuous fluoroscopy time: 10 min	Total time display: 99 min 59 sec., continuous fluoroscopy time: 10 min SAME
Pulsed Fluoroscopy	Max. 30 fps, grid-controlled.	Max. 30 fps, grid-controlled. SAME

7. **Summary of non-clinical testing:** This device has been tested and is certified to comply with the US Radiation Safety Performance Standard. Performance and safety testing was conducted by third party NRTL certified testing laboratories and the device was found to comply with the following FDA recognized standards:
   - IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint); IEC 60601-1 :2005+Corrigendum 1+Corrigendum 2+A1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance, FDA 19-4
   - IEC 60601-1-3:2008+A1 Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment FDA 12-269

- IEC 60601-1-6:2010+A1 General requirements for basic safety and essential performance – Collateral standard: Usability FDA 5-89
- IEC/EN 60601-2-28:2010 Medical electrical equipment – Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis FDA 12-204
- IEC 60601-2-54:2009+A1 Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy, FDA 12-296
- IEC 62304:2006 Medical device software – Software life cycle processes, FDA 13-32
- IEC 62366:2007+A1 Application of usability engineering to medical devices, FDA 5-114
- EN 60601-1-2:2015, IEC 60601-1-2:2014 Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests FDA 19-8

We consulted the following FDA guidance documents in the development of the FLUOROspeed: *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff;* and *Pediatric Information for X-ray Imaging Device Premarket Notifications.*

8. **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**.**

9. **Conclusion:** After analyzing standards compliance results and bench tests, it is the conclusion of Shimadzu Corporation that the MODIFIED FLUOROspeed 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.