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

Shimadzu Corporation
% Mr. Don Karle
Manager, Customer Service
20101 South Vermont Avenue
TORRANCE CA 90502-1328

March 6, 2015

Re: K142341
Trade/Device Name: X-ray TV System SonialVision G4
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: February 3, 2015
Received: February 11, 2015

Dear Mr. Karle:

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 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" (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 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,

Robert A Ochs

Robert Ochs, Ph.D.
Acting 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)*
K142341

Device Name
X-RAY TV SYSTEM 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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SECTION V: 510(k) Summary

The following information is submitted in accordance with the requirements of 21 CFR§807.92.

1) Date of Submission

July 30th, 2014

2) Submitter

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5) Device

Name of Device	: X-RAY TV SYSTEM SONIALVISION G4
Common Nam	: X-RAY RF SYSTEM
Classification Name	: Image-intensified fluoroscopic x-ray system (21 CFR§892.1650)
Classification Panel	: Radiology
Regulatory Class	: Class II
Product Code	: JAA

6) Predicate Device

Primary Predicate Device:
X-RAY TV SYSTEM SONIALVISION G4 (K131075)
SHIMADZU CORPOATION

Secondary Predicate Device:
Discovery XR656 with VolumeRad (Digital Tomosynthesis) (K132261)
GE Medical Systems, LLC.

No reference devices were used in this submission.

SECTION V: 510(k) Summary

7) Purpose of Submission

The purpose of this submission is to notify FDA of our intent to introduce a modified device of a legally marketed device, K131075 X-RAY TV SYSTEM SONIALVISION G4. The modification is to add “Tomosynthesis technique” to its indication for use, which is substantially equivalent to the similar indication for use of a legally marketed device, K132261 DISCOVERY XR656 WITH VOLUMERAD (Digital Tomosynthesis) manufactured by GE Medical Systems, LLC.

8) Device Description

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.

9) Intended Use

The SONIALVISION G4 is intended to be used for the fluoroscopy and radiography diagnosis. This system is operated and used by the physicians and/or X-ray technologists in the hospitals. The system is used for total patient population. This system is used for radiographic, fluoroscopic, angiographic and pediatric examinations.

10) 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.

11) Comparison of Technological Characteristics with the predicate devices

At a high level, new device and its primary predicate device are based on the following same technological elements:

- Energy emission to the patient – X-ray
- Power requirement, Environmental requirement
- Mechanism to generate X-ray,
- Mechanism to acquire, process and store image data
- Use of the same hardware components, user interfaces

The following technological differences exist between new and primary predicate device.

- Use of software processing for tomosynthesis
- Use of mechanism to acquire tomographic plane
- Clinical images resulted by tomosynthesis technique

12) Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Electromagnetic compatibility

Both new device and primary predicate device are in conformity with IEC60601-1-2. The difference is edition of the standard. Difference of edition of the standard does not affect safety and effectiveness.

Materials and Bio-compatibility testing

As there are no additional hardware components, there are no differences on materials and bio-compatibility between new device and primary predicate device. Both new device and primary predicate device are in conformity with ISO 10993-1:2009.

Electrical, Mechanical, Chemical and Thermal safety

As to these safeties, new device and primary predicate device are substantially equivalent by their conformed standards.

Software Verification and Validation Testing

Software verification and validation testing were conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." We identified the level of concern associated with new device and provided documentation consistent with that level. Based on our risk analysis of software, the difference does not affect its safety and effectiveness.

Non-clinical Performance Testing

For the tomosynthesis technique which is different from primary predicate device, we performed non-clinical performance testing between new device and secondary predicate device in accordance with the FDA Guidance "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging (SSXI) Devices". Accuracy of tomographic acquisition of two devices was measured, and phantom images of two devices were compared. As a result, we estimated that new device has equivalent performance to acquire images by tomosynthesis technique. The results of non-clinical performance testing demonstrate substantial equivalence to secondary predicate device in aspect of tomosynthesis capability.

Clinical Performance Testing

Per SSXI guidance, concurrence clinical study was executed by an U.S. certified Radiologist. Between new device and secondary predicate device, multiple clinical images taken by tomosynthesis technique were compared on several different anatomies. From the result of

overall clinical review, we concluded that new device is substantially equivalent to the secondary predicate device in aspect of its diagnostic capability.

Radiation safety

New device and primary predicate device is substantially equivalent by their conformities of CFR and IEC60601-1-3. Also, for additional “tomosynthesis technique”, non-clinical bench testing as well as clinical performance testing were executed with associated dose information of each image. The result of Performance Data demonstrates substantial equivalence to the secondary predicate device.

13) Conclusion

The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that new device should perform as intended in the specified use of tomosynthesis technique. Based on our risk analysis, the bench testing as well as clinical testing, the differences do not affect its clinical safety or effectiveness.

From the result of nonclinical and clinical testing discussed above, it is our conclusion that,

- New device is identical to the commercially available primary predicate device the X-RAY TV SYSTEM SONIALVISION G4, which was cleared on March 28, 2014 with K131075 except its tomosynthesis technique.
- Additional indication for use, tomosynthesis technique of new device is substantially equivalent to the commercially available secondary predicate device, Discovery XR656 with VolmeRad (digital tomosynthesis), which was cleared on November 18, 2013 with K132261. Additional indication for use does not introduce any new safety and effectiveness concern.
- Therefore, new device is as safe, as effective, and performs as well as or better than the predicate device(s).