MAR 2 8 2014

K131075

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SHIMADZU

SECTION V: 510(k) Summary

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

1) Date of Submission

April 2nd, 2013

2) Submitter

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4) Secondary Contact Person

Don Karle
SHIMADZU MEDICAL SYSTEMS
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Phone: 310-217-8855 ext 109
Email: karle@shimadzu-usa.com

5) The Device Name

Trade Name	X-RAY TV SYSTEM SONIALVISION G4
Common Name	X-RAY RF SYSTEM
Regulation Description	Image-intensified fluoroscopic x-ray system
Classification Panel	Radiology
CFR Section	21 CFR§892.1650
Device Class	Class II
Product Code	90 JAA

6) Legally Marketed Predicate Device

K052500	DAR-8000F

7) Description of the Device

The Shimadzu SONIALVISION G4 is a universal X-ray RF system offering radiographic, fluoroscopic and angiographic techniques. 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.

8) 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 X-ray technologist in a hospital. The system is used for total patient population. This system is used for radiographic, fluoroscopic, angiographic and pediatric examinations.

9) Indications for Use

The SONIALVISION G4 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 system is used for total patient population. This system is NOT intended to be used for Mammography screening. This system is NOT intended to be used for interventional procedure. This system is used for radiographic, fluoroscopic, angiographic and pediatric examinations. Stored images in this system can be used for re-monitoring, image processing, storing to optical media (CD/DVD), and sending to DICOM server.

Differences of indications are just additional information for usage, and those do not affect the safety and effectiveness of the device when used as labeled.

10) Technological Characteristics

The fundamental technologies of the SONIALVISION G4 are same as the predicate device. Modification was made in the material of Solid State Detector in the Digital Radiography System, which is similar to the predicate device regarding technical characteristic, performance and intended use. The safety and effectiveness is equivalent to the predicate device.

11) Non-clinical Performance Testing

Non-clinical performance testing was performed for the SONIALVISION G4 during product development, which includes verification and validation testing as well as phantom testing. The risk analysis was completed and risk controls implemented to mitigate identified hazards. The testing results support that all the software specifications have fulfilled the acceptance criteria.

The system complies to AAMI/ANSI ES 60601-1:2005, IEC 60601-2-54 Edition 1.0:2009 and other involved standards and applicable performance standards for radiation emitting products of this premarket submission.

We also conducted a performance bench test, comparing with image quality of both predicate device and modified device. Linearity, MTF, DQE and Density resolution of two detectors were measured and we estimated that both have enough performance to acquire X-ray images.

12) Clinical Testing

We performed concurrence study of clinical images between subject device and its predicate device, which was reviewed by an U.S. radiologist. The result of overall clinical review confirmed that new device is substantially equivalent to the predicate device in aspect of its diagnostic capability.

13) Conclusion

From the result of nonclinical and clinical testing discussed above, it is our conclusion that the SONIALVISION G4 is substantially equivalent to the commercially available predicate device DAR-8000f, which was cleared on Oct 17, 2005 with K052500.

This device is as safe, as effective, and performs as well as or better than the predicate device.

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

March 28, 2014

SHIMADZU CORPORATION
% Mr. Don Karle.
Manager, Customer Service
Shimadzu Medical Systems
20101 South Vermont Avenue
TORRANCE CA 90502-1328

Re: K131075
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 18, 2014
Received: February 21, 2014

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K131075

Device Name
SONIALVISION G4

Indications for Use *(Describe)*
-The SONIALVISION G4 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 system is used for total patient population.
- This system is NOT intended to be used for Mammography screening.
- This system is NOT intended to be used for interventional procedure.
- This system is used for radiographic, fluoroscopic, angiographic and pediatric examinations.
- Stored images in this system 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*