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

Toshiba Medical Systems Corporation
% Paul Biggins
Director Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
Tustin, California 92780

June 16, 2017

Re: K170909
Trade/Device Name: INFX-8000V, V6.40
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-Intensified Fluoroscopic X-Ray System
Regulatory Class: Class II
Product Code: OWB, JAA, IZI
Dated: March 24, 2017
Received: March 28, 2017

Dear Paul Biggins:

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,

For

Robert A. Ochs, 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170909

Device Name
INFX-8000V, Version 6.4

Indications for Use *(Describe)*

This device is a digital radiography/fluoroscopy system used in a diagnostic interventional angiography configuration. The system is indicated for use in diagnostic and angiographic procedures for blood vessels in the heart, brain, abdomen and lower extremities.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Device Act 1990 and 21 CFR § 807.92

1. **CLASSIFICATION and DEVICE NAME**

Classification Name	**Solid State X-ray System, Interventional**
Regulation Number	**21 CFR 892.1650 (Class II)**
Product Code	**OWB - Interventional Fluoroscopic X-ray System**
Trade Proprietary Name	**Infinix**
Model Number	**INFX-8000V, V6.40**

2. **SUBMITTER'S NAME**

Toshiba Medical Systems Corporation (TMSC)
1385 Shimoishigami
Otawara-Shi, Tochigi-ken, Japan 324-8550

3. **OFFICIAL CORRESPONDENT**

Akinori Hatanaka
Senior Manager, Regulatory Affairs and Vigilance

4. **CONTACT PERSON, U.S. AGENT and ADDRESS**

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5. **MANUFACTURING SITE**

Toshiba Medical Systems Corporation (TMSC)
1385 Shimoishigami
Otawara-shi, Tochigi 324-8550, Japan

6. **ESTABLISHMENT REGISTRATION**

9614698

7. **DATE PREPARED**

March 24, 2017

8. **DEVICE NAME**

INFX-8000V, V6.40

9. **TRADE NAME**

INFX-8000V, V6.40

10. CLASSIFICATION NAME

Interventional Fluoroscopic X-ray System

11. CLASSIFICATION PANEL

Radiology

12. DEVICE CLASSIFICATION

Class II (per 21 CFR 892.1650)

13. PRODUCT CODE / DESCRIPTION

Product Code: OWB – Interventional Fluoroscopic X-ray System

14. PERFORMANCE STANDARD

This device conforms to applicable Performance Standards for Ionizing Radiation Emitting Products [21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard].

15. PREDICATE DEVICE

INFX-8000V, V6.35 (K162614)

Product	Marketed by	510(k) Number	Clearance Date
INFX-8000V, V6.35	Toshiba America Medical Systems	K162614	October 17, 2016

16. REASON FOR SUBMISSION

Modification of a cleared device

17. SUBMISSION TYPE

Traditional

18. DEVICE DESCRIPTION

INFX-8000V, V6.40, is an X-ray system that is capable of radiographic and fluoroscopic studies and is used in an interventional setting. The system consists of a C-arm, which is equipped with an X-ray tube, beam limiter and X-ray receptor, X-ray controller, computers with system and processing software, and a patient radiographic table. This system offers an optional hybrid (aSi/CMOS) 12 inch flat panel detector (TFP-1200C) to provide high definition (HD) imaging.

19. INDICATIONS FOR USE

This device is a digital radiography/fluoroscopy system used in a diagnostic and interventional angiography configuration. The system is indicated for use in diagnostic and angiographic procedures for blood vessels in the heart, brain, abdomen and lower extremities.

20. SUMMARY OF CHANGE(S)

This notification is being submitted to inform the Food and Drug Administration of Toshiba Medical System intent to market a new image receptor, TFP-1200C. This notification contains the required information for the hardware change (primary) and the software changes required to support this change in hardware (secondary)

21. SAFETY

The device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820 and ISO 13485 Standards. This device is in conformance with the applicable parts of the IEC60601-1 standards, its collateral standards and particular standards; IEC 60601-2-43 and IEC60601-2-28. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR §1020, that apply to this device, will be met and reported via product report.

LIST OF APPLICABLE STANDARDS

- IEC60601-1:2005
- IEC60601-1-2:2007
- IEC60602-1-3: 2008
- IEC60601-1-6: 2010
- IEC60601-2-28: 2010
- IEC60601-2-43:2010
- IEC62304:2006
- IEC62366:2007

Testing of this device demonstrated that the radiation output does not exceed the normal mode of operation limit of 88mGy/min as described in the Federal Standard. In order to reduce the risk of unnecessary radiation exposure when the system is configured with TP-1200C High Definition Detector the Toshiba XDIF-DTS802 Dose Tracking System is incorporated in the configuration. Additionally, Live Zoom is not allowed in HD mode and requires an FOV of 6" or greater.

22. TESTING

This submission contains test data that demonstrates that the system modifications result in performance that is equal to or better than the predicate system. Testing of the modified system was conducted in accordance with the applicable standards published by the International Electromechanical Commission (IEC) for Medical Devices and XR Systems. Additional testing is provided per FDA Guidance "Guidance for the Submission of 510(k)'s for Solid State X-ray Imaging Systems." Software Documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission. Additionally, the design controls used for this device included risk management and all known risks were mitigated to an acceptable level.

Bench Testing was conducted to determine that equivalent or improved imaging performance resulted when compared to the predicate device. This testing included spatial resolution, low contrast resolution, dynamic range, artifacts and contrast. The results of this testing provided evidence that the modification to the predicate device did result in equivalent or improved performance when compared to the predicate.

23. SUBSTANTIAL EQUIVALENCE

This device is substantially equivalent to the INFX-8000V, V6.35, (K162614), marketed by Toshiba America Medical Systems. INFX-8000V, V6.40, includes a new Solid State Image receptor that is a continuum of previously introduced devices of this nature. The basic system

configuration, method of operation, base software and manufacturing process remain unchanged from the cleared device. There are no new indications for use or intended use of the device.

24. CONCLUSION

The subject device is substantially equivalent to the INFX-8000V, V6.35, which was cleared via Pre-Market Notification 510(k), K162614. The INFX-8000V, V6.40, incorporates modifications to the cleared device which include a new solid state imaging receptor and software modifications required to support the hardware. The changes to this device do not alter the indications for use or the intended uses associated with the previously cleared device, as described in the labeling. It is the contention of Toshiba that all new safety issues have been addressed in the design of this change and that adequate evidence of this is presented with this submission.