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

October 17, 2016

Toshiba Medical Systems Corporation
% Ms. Janine F. Reyes
Manager, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K162614
Trade/Device Name: Infinix, INFX-8000V, V6.35
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA, IZI
Dated: September 16, 2016
Received: September 19, 2016

Dear Ms. Reyes:

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,

For

Robert 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

Reset Form

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K162614

Device Name

Infinix, INFX-8000V, V6.35

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)

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)*

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**

Regulation Name	**Image-Intensified Fluoroscopic X-ray System**
Regulation Number	**21 CFR 892.1650 (Class II)**
Product Code	**OWB - Interventional Fluoroscopic X-ray System (primary)** **JAA - Image-Intensified Fluoroscopic X-Ray System (secondary)** **IZI – System, X-ray, Angiographic (secondary)**
Trade Proprietary Name	**Infinix, INFX-8000V, V6.35**
Model Number	**INFX-8000V, V6.35**

2. **SUBMITTER'S NAME**

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

3. **OFFICIAL CORRESPONDENT**

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5. **MANUFACTURING SITE**

Toshiba Medical Systems Corporation (TMSC)
1385 Shimoishigami
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6. **ESTABLISHMENT REGISTRATION**

9614698

7. **DATE PREPARED**

September 16, 2016

8. **DEVICE NAME**

Infinix, INFX-8000V, V6.35

9. TRADE NAME

INFX-8000V, V6.35

10. CLASSIFICATION NAME

Interventional Fluoroscopic X-ray System
Image-Intensified Fluoroscopic X-Ray System
System, X-ray, Angiographic

11. CLASSIFICATION PANEL

Radiology

12. DEVICE CLASSIFICATION

Class II (per 21 CFR 892.1650)

13. PRODUCT CODE / DESCRIPTION

Primary Product Code: OWB – Interventional Fluoroscopic X-ray System
Secondary Product Codes: JAA - Image-Intensified Fluoroscopic X-Ray System
Secondary Product Code: IZI – System, X-ray, Angiographic

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, V6.20 (K152696)

Product	Marketed by	510(k) Number	Clearance Date
INFX-8000V, V6.20	Toshiba America Medical Systems	K152696	January 12, 2016

16. REASON FOR SUBMISSION

Modification of a cleared device

17. SUBMISSION TYPE

Special 510(k)

18. DEVICE DESCRIPTION

INFX-8000V, V6.35, 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.

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 submission is to report virtual ROI function and the addition of pulse width modulation during low contrast image acquisition.

- **Virtual ROI function:** this function enables the display of virtual X-ray field before X-ray exposure.
- **Pulse width modulation during low contrast image (LCI) acquisition:** pulse width modulation enables uniform brightness of projection data during acquisition.
- Grid material change from an aluminum to a fiber grid (TFP-1216A/A1 and TFP-1216A/C1)
- High-speed LCI acquisition feature of TFP-1200A

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

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 included spatial resolution, low contrast resolution, dynamic range, DQE, MTF, artifacts/contrast/dynamic range of DSA, CNR, S/N ratio and density resolution. 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.

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.

23. SUBSTANTIAL EQUIVALENCE

This device is substantially equivalent to the INFX-8000V, V6.20, (K152696), marketed by Toshiba America Medical Systems. INFX-8000V, V6.35, includes virtual ROI function and the addition of pulse width modulation during low contrast image acquisition. 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, V6.20, which was cleared via Pre-Market Notification 510(k), K152696. The INFX-8000V, V6.35, incorporates modifications to the cleared device which include virtual ROI function and the addition of pulse width modulation during low contrast image acquisition. 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.