



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

January 12, 2016

Re: K152696
Trade/Device Name: INFX-8000V, V6.20
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA and IZI
Dated: December 16, 2015
Received: December 18, 2015

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style and is positioned above the typed name.

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

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

Reset Form**Indications for Use**

510(k) Number (if known)

K152696

Device Name

INFX-8000V, V6.20

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)

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) – SUMMARY OF SAFETY AND EFFECTIVENESS

1. CLASSIFICATION and DEVICE NAME:

Classification 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 - System, X-Ray, Fluoroscopic, Image-Intensified (secondary) IZI - System, X-Ray, Angiographic (secondary)
Trade Proprietary Name:	Infinix
Model Number:	INFX-8000V, V6.20

2. ESTABLISHMENT REGISTRATION: 9614698

3. U.S. AGENT and ADDRESS:

Official Correspondent/U.S. Agent:

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Director, Regulatory Affairs
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Contact Person:

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Establishment Name and Address:

Toshiba America Medical Systems, Inc. (TAMS)
2441 Michelle Drive
Tustin, CA 92780

4. MANUFACTURING SITE:

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

5. DATE PREPARED:

September 18, 2015

6. TRADE NAME(S):

INFX-8000V, V6.20 [Infinix CC-i]

7. COMMON NAME:

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

8. REGULATION NAME:

Image-Intensified Fluoroscopic X-Ray System

9. DEVICE CLASSIFICATION:

Class II (per 21 CFR 892.1650)

10. PRODUCT CODE / DESCRIPTION:

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

11. PERFORMANCE STANDARD:

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

12. PREDICATE DEVICE:

INFX-8000V, with Wireless Footswitch (K143225)

Product	Marketed by	510(k) Number	Clearance Date
INFX-8000V, with Wireless Footswitch	Toshiba America Medical Systems	K143225	January 9, 2015

13. REASON FOR SUBMISSION:

Modification of a cleared device

14. SUBMISSION TYPE:

Traditional 510(k)

15. DEVICE DESCRIPTION:

INFX-8000V, V6.20, 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.

The device software is used to control the system, set X-ray conditions, acquire digital images from the X-ray detector, display images on the monitors, perform image processing and recording. This X-ray system has a wireless footswitch option. This X-ray system does not have wireless transmission of data.

16. INDICATIONS FOR USES:

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.

17. SUMMARY OF CHANGE(S)

This submission is to report improvements to the Auto Pixel Shift (APS) algorithm, the addition of Spot ROI Fluoroscopy and Clinical Mode.

- i. Auto Pixel Shift (APS) – the correction accuracy of the improved APS algorithm was confirmed to be equal to or greater than the correction accuracy of the current APS algorithm.
- ii. Spot ROI (region of interest) Fluoroscopy – allows for peripheral region visualization outside of the area of interest.
- iii. Clinical Mode – provides preset 2D roadmap display settings to enhance user workflow during common clinical cases.

18. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the INFX-8000V, with Wireless Footswitch, (K143225), marketed by Toshiba America Medical Systems. INFX-8000V, V6.20, includes improvements to the Auto Pixel Shift (APS) algorithm, the addition of Spot ROI Fluoroscopy and Clinical Mode. 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.

Item	Predicate Device: INFX-8000V with Wireless Footswitch (K143225)	Subject Device: INFX-8000V, V6.20	Notes
Intended 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.	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.	Same
Operation Principles	The high voltages output by the X-ray generator are supplied to the X-ray tube, and the X-ray beams are generated. The X-ray beams that have passed through the patient are converted to electrical signals by the flat panel detector based on the X-ray scintillation effect. The signals are then sent to the digital imaging subsystem as digital image signals, and digital images are processed/recorded. In addition, the images are displayed on the monitor and are transferred to the network.	The high voltages output by the X-ray generator are supplied to the X-ray tube, and the X-ray beams are generated. The X-ray beams that have passed through the patient are converted to electrical signals by the flat panel detector based on the X-ray scintillation effect. The signals are then sent to the digital imaging subsystem as digital image signals, and digital images are processed/recorded. In addition, the images are displayed on the monitor and are transferred to the network.	Same

Item	Predicate Device: INFX-8000V with Wireless Footswitch (K143225)	Subject Device: INFX-8000V, V6.20	Notes
Auto Pixel Shift	Available	Algorithm Improvement	Change
Spot ROI Fluoroscopy	Not Available	Available	Change
Clinical Mode	Not Available	Available	Change
Roadmap Function	2D Roadmap 3D Roadmap Multimodality Roadmap	2D Roadmap 3D Roadmap Not Available	Change

19. 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 60601-1:2005, IEC 60601-1-2:2007, IEC 60601-1-3:2008, IEC 60601-1-6:2010, IEC 60601-2-28:2010, IEC 60601-2-43:2010, IEC 62304:2006, IEC 62366:2007. 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.

20. 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 Electrotechnical 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.

21. CONCLUSION

The subject device is substantially equivalent to the INFX-8000V, with Wireless Footswitch, which was cleared via Pre-Market Notification 510(k), K143225. The INFX-8000V, V6.20, incorporates modifications to the cleared device which include improvements to the Auto Pixel Shift (APS) algorithm, the addition of Spot ROI Fluoroscopy and Clinical Mode. 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.