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

January 15, 2016

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

Re: K152697
Trade/Device Name: INFX-8000C, V6.20
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB, JAA
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,

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

Indications for Use

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

510(k) Number *(if known)*
K152697

Device Name
INFX-8000C, V6.20

Indications for Use *(Describe)*
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.

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 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)**
Trade Proprietary Name:	**Infinix**
Model Number:	**INFX-8000C, V6.20**

2. ESTABLISHMENT REGISTRATION: 9614698

3. CONTACT PERSON, U.S. AGENT and ADDRESS:

Official Correspondent/U.S. Agent:
Paul Biggins
Director, Regulatory Affairs
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Contact Person:
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Manager, Regulatory Affairs
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janine.reyes@toshiba.com

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-8000C, 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

8. DEVICE CLASSIFICATION:
Class II (per 21 CFR 892.1650)

9. PRODUCT CODE / DESCRIPTION:
Primary Product Code: OWB - Interventional Fluoroscopic X-Ray System
Secondary Product Code: JAA - System, X-Ray, Fluoroscopic, Image-Intensified

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

11. PREDICATE DEVICE:
INFX-8000C, w/Spot Fluoroscopy Option (K113052)

TABLE 1: Predicate Device

Product	Marketed by	510(k) Number	Clearance Date
INFX-8000C, w/Spot Fluoroscopy Option	Toshiba America Medical Systems	K113052	November 22, 2011

12. REASON FOR SUBMISSION:
Modification of a cleared device

13. SUBMISSION TYPE:
Traditional 510(k)

14. DEVICE DESCRIPTION:

INFX-8000C, 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.

15. SUMMARY OF INTENDED 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.

16. SUMMARY OF CHANGE(S)

This submission is to report the following items have been changed:

a. The current flat panel detectors have been modified for improved DQE performance, model numbers are:

   i. Model Number: Old TFP-800A; new TFP-800A/C1 (20cm x 20cm)
   ii. Model Number: Old TFP-1216A; new TFP-1216A/C1 (30cm x 40cm)

      1. Scintillator thickness increased
      2. ADC Bus from 14 to 16 bits
      3. ASIC improvements
      4. DQE performance enhancement

b. New C-arm support assembly (CAS-930A)

TABLE 2: Changes to INFX-8000C since 510(k) Clearance (K113052)

Change	**Predicate Device: INFX-8000C, with Spot Fluoroscopy Option (K113052)**	**Subject Device: INFX-8000C, V6.20**
C-arm Support**	CAS-830B/A1	CAS-830B /A1 CAS-930A
C-arm Sliding Angle**	RAO 90° LAO 50°	RAO 90° LAO 50° RAO 120° LAO 90°
SID Range*	90cm to 120cm (30cm x 40cm FPD, 20cm x 20cm FPD)	90cm to 120cm (30cm x 40cm FPD) 90cm to 125cm (20cm x 20cm FPD, 30cm x 30cm FPD)
X-ray Tube Assembly*	Liquid metal bearing Ball bearing	Liquid metal bearing
Anode Heat Storage Capacity*	3.0MHU (Liquid metal bearing) 1.8MHU (Ball bearing)	3.0MHU (Liquid metal bearing)
Focal Spot Size*	0.5/0.8 mm (Liquid metal bearing) 0.3/0.6/1.0 mm (Liquid metal bearing) 0.3/0.5/0.8 mm (Ball bearing) 0.3/0.6/1.0 mm (Ball bearing)	0.5/0.8 mm (Liquid metal bearing) 0.3/0.6/1.0 mm (Liquid metal bearing) 0.4/0.6/0.9 mm (Liquid metal bearing)
Beam Limiting Device X-ray Exposure Field*	Cardiac: 230mm x 230mm Maximum (on the plane 870 mm from the focus) Angiography: 406mm x 406mm Maximum (on the plane 930 mm from the focus)	Cardiac: 340mm x 340mm Maximum (on the plane 900 mm from the focus) Angiography: 400mm x 400mm Maximum (on the plane 900 mm from the focus)
Detector Size	20cm x 20cm 30cm x 40cm	20cm x 20cm** 30cm x 40cm** 30cm x 30cm*
DQE**	65% or more (0 lp/mm) (20cm x 20cm, 30cm x 40cm)	65% or more (0 lp/mm) or 77%±5% (0 lp/mm) (20cm x 20cm, 30cm x 30cm, 30cm x 40cm)
Fluoroscopic Monitor/ Reference Monitor*	19.0 inch	19.0 inch 56.2 inch
Roadmap Function*	2D Roadmap	2D Roadmap 3D Roadmap
Footswitch*	Wired	Wired Wireless
Connection with CT System*	Not Available	Available
Combined with CT System for IVR-CT*	Not Available	CGBA-033A, Aquilion ONE ViSION CGBA-032A, Aquilion PRIME

*Cleared by previous regulatory affairs action
**Part of this Pre-Market Notification 510(k) submission

17. SUBSTANTIAL EQUIVALENCE:

This device is substantially equivalent to the **I**NFX-8000C, w/Spot Fluoroscopy Option (K113052), marketed by Toshiba America Medical Systems. INFX-8000C, V6.20, includes incremental improvements to the cleared flat panel detectors (TFP-800A and TFP-1216A) and a new C-arm support assembly (CAS-930A). 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.

18. 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.

19. TESTING:

This submission contains test data that demonstrates 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 DS and horizontal streak noise. The results of this testing demonstrate equivalent or increased performance when compared to the predicate device.

Testing of the modified system was conducted in accordance with the applicable standards published by the International Electrotechnical Commission (IEC) for Medical Devices and X-ray Systems: 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. 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.

20. CONCLUSION

The subject device is substantially equivalent to the INFX-8000C, w/Spot Fluoroscopy Option, which was cleared via Pre-Market Notification 510(k), K113052. The INFX-8000C, V6.20, incorporates modifications to the cleared device which include a new C–arm support assembly and incremental improvements to the cleared flat panel detectors. While these modifications do introduce new technological characteristics, they did not raise different questions of Substantial Equivalence compared to the predicate device. Documentation of the design change process, as well as non-clinical testing data as described in Section 19 “Testing”, demonstrate equivalent or improved performance.

The modifications incorporated into the INFX-8000C, V6.20, 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.