Department of Health & Human Services  

Food and Drug Administration  

Toshiba Medical Systems Corporation  
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  

January 15, 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,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure
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.

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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Food and Drug Administration  
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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:

<table>
<thead>
<tr>
<th>Classification Name:</th>
<th>Image-Intensified Fluoroscopic X-Ray System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Number:</td>
<td>21 CFR 892.1650 (Class II)</td>
</tr>
<tr>
<td>Product Code</td>
<td>OWB - Interventional Fluoroscopic X-ray System (primary)</td>
</tr>
<tr>
<td>Trade Proprietary Name:</td>
<td>Infinix</td>
</tr>
<tr>
<td>Model Number:</td>
<td>INFX-8000C, V6.20</td>
</tr>
</tbody>
</table>

2. ESTABLISHMENT REGISTRATION: 9614698

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

   Official Correspondent/U.S. Agent:
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000
   Fax: (714) 730-1310
   paul.biggins@toshiba.com

   Contact Person:
   Janine Reyes
   Manager, Regulatory Affairs
   (714) 669-7853
   Fax: (714) 730-1310
   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

10. PERFORMANCE STANDARD:
    This device conforms to applicable Performance Standards for Ionizing Radiation Emitting

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

   **TABLE 1:** Predicate Device

<table>
<thead>
<tr>
<th>Product</th>
<th>Marketed by</th>
<th>510(k) Number</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>INFX-8000C, w/Spot Fluoroscopy Option</td>
<td>Toshiba America Medical Systems</td>
<td>K113052</td>
<td>November 22, 2011</td>
</tr>
</tbody>
</table>

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)

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

Toshiba Medical Systems Corporation
Traditional Pre-Market Notification 510(k)
INFX-8000C, V6.20
**17. SUBSTANTIAL EQUIVALENCE:**

This device is substantially equivalent to the **INFX-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:**


**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.

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.