Toshiba America Medical Systems, Inc.
Pre-Market Notification 510(k) for INFX-8000V w/3D Roadmapping

510(k) Summary

K101868

SEP. 07 2010

Date:	June 30, 2010
Submitter's Name:	Toshiba America Medical Systems, Inc.
Submitter's Address:	P.O. Box 2068, 2441 Michelle Drive, Tustin, CA 92781-2068
Submitter's Contact:	Paul Biggins, Director Regulatory Affairs (714)730-5000
Establishment Registration Number:	2020563
Device Proprietary Name:	INFX-8000V (Infinix CF*i* and Infinix VF*i*)
Common Name:	Electrostatic Fluoroscopic x-ray System) [Fed. Reg. No. 892.1650, Pro. Code: 90MQB]
Regulatory Class:	II (per 21 CFR 892.1650)
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Predicate Devices	Toshiba, INFX-8000V GE Innova 2100,3100, 4400 w/Innova 3D or InnovaSpin Siemens In Space 3D Option
Reason For Submission	Addition of 3D Road-mapping Function

Description of this Device:
These systems are single or dual plane systems that employ x-rays to obtain fluoroscopy or radiography images of the body. The system is comprised of a computer system, support arms that contain the tube and solid state detector (either one or two), x-ray generator and a patient table.

The 3D Road-mapping function is an extension of the already existing 2D Road-mapping function both of which overlay the fluoroscopic image on the DSA image on the system monitor.

Summary of Intended Uses:
This device is a digital x-ray system configured for use as a diagnostic x-ray angiography system. This x-ray angiography system is used for diagnostic and interventional procedures for cardiac blood vessels, cerebral blood vessels, abdominal blood vessels and lower extremities.

Technological Characteristics:
This device employs similar materials and processes as found in the predicate device. The device produces ionizing radiation that is employed to generate fluoroscopic and radiographic images of the anatomy.

Safety and Effectiveness Concerns:
This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. 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 an initial report. Additionally this system is in conformance with the applicable parts of the IEC 60601-1 {applicable portions}; IEC 60601-2-32, and IEC 60601-2-28. - Medical Device Safety standards.

Furthermore, the system is subjected to a risk management during the design stages to mitigate risks appropriately. The risks may be mitigated through hardware, software or user information as deemed appropriate by the level of risk and appropriate mitigation strategies.

Substantial Equivalence:

The INFX-8000V with 3D Road-mapping is of comparable type and substantially equivalent to:

Toshiba, INFX-8000V; K081852
GE, Innova 2100, 3100, 4400 w/Innova 3D or InnovaSpin; K054212
Siemens, In Space 3D Option; K011447

Therefore the INFX-8000V complies with the same or equivalent standards and has the same intended use as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUL 30 2012

Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K101868
Trade/Device Name: infx-8000v; Infinix CFi and Infinix-VFi
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: August 12, 2010
Received: August 13, 2010

Dear Mr. Biggins:

This letter corrects our substantially equivalent letter of September 7, 2010.

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

SEP 07 2010

510(k) Number (if known):

Device Name: INFX-8000V; Infinix-CF*i* and Infinix- VF*i*

Indications for Use:

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

3D Road-mapping function to assist in the planning and execution of interventional procedures

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ OIVD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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