K041027

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MAY 1 4 2004

510(k) SUMMARY

1. **DEVICE NAME:** Solid State X-Ray Imager
   Model Name: DFP-8000D / FPD
   Trade/Proprietary Name: Digital Radiography System with Flat Panel Detector (FPD)

2. **ESTABLISHMENT REGISTRATION:** 2020563

3. **U.S. Agent Name and Address:** TOSHIBA AMERICA MEDICAL SYSTEMS,INC.
   2441 MICHELLE DRIVE
   TUSTIN, CA 92780

   Contact Person: Michaela Mahl
   Senior Regulatory Affairs Specialist
   (714) 730 - 5000

4. **Manufacturing Site:** TOSHIBA MEDICAL SYSTEMS CORPORATION
   1385 Shimoishigami
   Otawara-shi, Tochigi 324-8550, Japan

5. **Date of Submission:** April 08, 2004

6. **Predicate Device:** DFP-8000D (K013608) with Image Intensifier (K993038)

7. **DEVICE DESCRIPTION**
   This equipment is a digital radiography with Flat Panel Detector (FPD) used in diagnostic X-ray angiography system configuration.
   This equipment processes, displays, and records digital images obtained from the Flat Panel Detector, and it replays the recorded images.

8. **SUMMARY of INTENDED USE**
   This device is a digital radiography used in diagnostic X-ray angiography system configuration.

   This X-ray angiography system is indicated for use in diagnostic and interventional cardiac examinations.
   It is intended to replace images obtained through the image intensifier technology.

9. EQUIVAALENCY INFORMATION

TOSHIBA Medical Systems Corporation believes that the new Digital Radiography System, model DFP-8000D/FDP is substantially equivalent to the current Digital Radiography System, model DFP-8000D (K013608) with Image Intensifier (model RTP9211J-G11) (K993038) except for the new Flat Panel Detector (FPD).

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

Toshiba America Medical Systems, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street NW
BUFFALO MN 55313

AUG 23 2013

Re: K041027
Trade/Device Name: Digital Radiography Systems with Flat Panel Detector, Model DFP-8000D/FDP
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI and MQB
Dated: April 15, 2004
Received: April 21, 2004

Dear Mr. Job:

This letter corrects our substantially equivalent letter of May 14, 2004.

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

TAB B

510(k) Number (if known): K041027

Device Name: Digital Radiography System with Flat Panel Detector, Model DFP-8000D/FDP

Indications for Use:

This device is a digital radiography system used in diagnostic X-ray angiography system configuration.
This X-ray angiography system is indicated for use in diagnostic and interventional cardiac examinations.
It is intended to replace images obtained through the image intensifier technology.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K041027