FUJIFILM
Fujifilm Medical Systems, USA

K121499

510(k) Summary

Date: October 29, 2012

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, CT, 06902, USA

NOV 20 2012

Contact Person:

Name: Katherine Y. Choi, RAC
Title: Regulatory Affairs Specialist
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Identification of the Proposed Device:

Proprietary/Trade Name: FUJIFILM Tomosynthesis option for FDR AcSelerate Stationary X-ray System
Common Name: Stationary X-ray System
Device Class: Class II
Review Panel: Radiology

Classification Information:

Classification Name	CFR Section	Product Codes
Stationary X-ray System	21 CFR 892.1680	KPR
Solid State X-ray Imager (Flat Panel/Digital Imager)	21 CFR 892.1650	MQB
Tomographic X-ray System	21 CFR 892.1740	IZF

I. INDICATIONS FOR USE

Fujifilm's Tomosynthesis option is intended to acquire tomographic images of human anatomy and to be used with Fujifilm's DR X-ray systems. Tomosynthesis is used to synthesize tomographic slices from a single tomographic sweep. It is not intended for mammographic applications.

II. DEVICE DESCRIPTION

Tomosynthesis is an advanced radiographic application that produces individual coronal "slice" images through an anatomical region of interest (ROI). To produce these slices, multiple projection radiographic images are acquired in rapid succession as the X-ray tube sweeps and rotates across the ROI. Once acquired, these projection images are subject to image processing that registers and reconstructs them into individual tomographic slices.

Tomosynthesis provides visualization of human anatomy by
1. Removing overlying anatomical structures, which could otherwise obscure a structure of interest by superimposition in a 2 dimensional presentation, and
2. Producing a number of slice images throughout the entire volume of the anatomy.

Tomosynthesis will be available as an option to the legally marketed FDR AcSelerate Stationary X-ray System (K093427) with some modifications. To support Tomosynthesis application, the new Tomosynthesis software and new system component called Pre-Processing Unit (PPU) are required along with the upgraded version of the FDX Console. The new 17x17" CsI (cesium iodide) built-in detector, which replaced the previous a-Se (amorphous selenium) 17x17" FPD, will be used for Tomosynthesis.

III. SUMMARY OF STUDIES

The proposed device conforms to the following voluntary standards as applicable to the system.

IEC 60601-1	Medical electrical equipment - Part 1: General requirements for safety
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-3	Medical electrical equipment - Part 1-3: General requirements for safety - Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment
IEC 60601-1-4	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral Standard: Programmable Electrical Medical systems
IEC 60601-2-7	Medical electrical equipment - Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic X-ray generators
IEC 60601-2-28	Medical electrical equipment - Part 2-28: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis
IEC 60601-2-32	Medical electrical equipment - Part 2-32: Particular requirements for the safety of associated equipment of X-ray equipment
IEC 60825-1	Safety of laser products - Part 1: Equipment classification and requirements
UL 60601-1	Medical electrical equipment - Part 1: General requirements for safety
DICOM	Digital Imaging and Communications in Medicine (DICOM)

Various bench testing in addition to software verification and validation testing to evaluate the Tomosynthesis performance were completed and the results were satisfactory. Additionally the image quality evaluation demonstrated the proposed Tomosynthesis' diagnostic image quality is substantially equivalent to the legally marketed devices, including the existing linear tomography capability of the AcSelerate system. The supporting documents are enclosed in the submission along with sample images.

IV. SUBSTANTIAL EQUIVALENCE

The proposed device, FUJIFILM Tomosynthesis option for FDR AcSelerate Stationary X-ray System is substantially equivalent to the following legally marketed devices.

Legally Marketed Device	510(k) #
Revolutionary XR/d with Tomosynthesis	K051967
FDR AcSelerate Stationary X-ray System	K093427

The proposed device has the very similar Indications for Use, functional and technical requirements as the predicate device, K051967. In addition, most X-ray system and X-ray generator specifications remain the same as the previously-cleared FDR AcSelerate System in K093427.

V. CONCLUSION

We concluded the proposed FUJIFILM Tomosynthesis option for FDR AcSelerate Stationary X-ray System is as safe and effective as the legally marketed devices based upon the studies summarized above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO-66
Silver Spring, MD 20993-002

November 20, 2012

Ms. Katherine Choi
Regulatory Affairs Specialist
FUJIFILM Medical Systems USA, Inc.
419 West Avenue
STAMFORD CT 06902

Re: K121499
Trade/Device Name: FUJIFILM Tomosynthesis option for FDR AcSelerate Stationary X-ray System
Regulation Number: 21 CFR 892.1740
Regulation Name: Tomographic x-ray system
Regulatory Class: II
Product Code: IZF
Dated: October 29, 2012
Received: November 1, 2012

Dear Ms. Choi:

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 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health 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 -S

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

Enclosure

510(k) Number (if known): K121499

Device Name: FUJIFILM Tomosynthesis for FDR AcSelerate Stationary X-ray System

Indications for Use:

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Janine M. Morris -S
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(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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