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

FUJIFILM Medical Systems U.S.A., Inc.
% Dharaben Desai
Sr. Regulatory Affairs Specialist
419 West Avenue
STAMFORT CT 06902

August 31, 2017

Re: K163624
Trade/Device Name: Dynamic Visualization II Image Processing Option for the FDX Console (DR-ID300CL of the DR-ID600)
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: May 23, 2017
Received: May 24, 2017

Dear Dharaben Desai:

This letter corrects our substantially equivalent letter of June 30th, 2017. 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

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)*

Device Name
Dynamic Visualization II Image Processing Option for the FDX Console (DR-ID300CL of the DR-ID600).

Indications for Use *(Describe)*

Dynamic Visualization II Image Processing is an optional software for the FDX Console, intended to provide optimized image quality over a wide range of patient thicknesses, especially for bariatric imaging. The device is not intended for mammography use.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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

Dynamic Visualization II Image Processing Option for the FDX Console (DR-ID300CL of DR-ID600)

Date: May 23, 2017

Submitter's Information:

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

Contact Person:

Name: Dharaben Desai
Title: Sr. Regulatory Affairs Specialist
Telephone: (203) 276-3445
Facsimile: (203) 602-3785

Identification of the Device:

Proprietary/Trade Name:	Dynamic Visualization II Image Processing Option for the FDX Console (DR-ID300CL of DR-ID600)
Classification Name:	Stationary X-ray system
Regulations Number:	21 CFR 892.1680
Product Codes:	MQB
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Flat Panel Digital Detector System

Identification of the Legally Marketed Predicate Device:

FDR D-EVO Flat Panel Detector System (DR-ID600) with Improved Virtual Grid Software, K153464 cleared 4/8/2016

I. DEVICE DESCRIPTION

Fujifilm's FDR D-EVO Flat Panel Detector System (DR-ID600) is a portable digital detector system that interfaces with, and acquires and digitizes x-ray exposures, from standard radiographic systems. The FDR D-EVO is designed to be used in any environment that would typically use a radiographic cassette for examinations of adults, pediatrics and neonates. The detector models support both wireless and wired/tethered data communication between the detector and the system. Detectors can be placed in a wall bucky for upright exams, a table bucky for recumbent exams, or removed from the bucky for non-grid exams. The Acquisition Workstation for the DR-ID600 is the FDX Console. Dynamic Visualization II Image Processing (DVII) is optional software included in v9.0 of the FDX Console. The FDX Console and Dynamic Visualization II software may be used with Fujifilm DR and CR X-ray systems.

Dynamic Visualization II is an enhanced version of Fujifilm's Dynamic Visualization™ (DV) image processing software. The enhancements made to DVII are designed to provide optimized image quality over a wide range of patient thicknesses, and can be particularly useful when imaging bariatric patients.

DVII uses the same image processing sequence as the predicate DV, but the EDR (Exposure Data Recognition) and MFP (Multi-objective Frequency Processing) algorithms have been modified. When compared to the current EDR and MFP algorithms, the corresponding new algorithms (EDR2, MFP2) have been modified as follows:

EDR2 – to identify and optimize various anatomic structures in an acquired image prior to the subsequent application of contrast and sharpness image processing steps, EDR2 uses a feature recognition method as opposed to conventional EDR's histogram analysis method.

MFP2 – similar to MFP, MFP2 sharpens and balances contrast in anatomic structures in an image after being subject to Exposure Data Recognition. MFP2 uses additional low frequency tables and a combination of automatic and preset dynamic range control operations.

II. INDICATIONS FOR USE

Dynamic Visualization II Image Processing is an optional software for the FDX Console, intended to provide optimized image quality over a wide range of patient thicknesses, especially for bariatric imaging. The device is not intended for mammography use.

III. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

FDR D-EVO FPD System (DR-ID600) continues to offer 600 series detectors with two different scintillator materials - GOS (Gadolinium oxysulfide) or CsI (Cesium Iodide) - and various detector sizes to choose from. All detector characteristics including indirect conversion method using Fujifilm's unique Irradiated Side Sampling (ISS) technology, pixel pitch (150µm), resolution (16 bit), DQE (Detective Quantum Efficiency) measurements, MTF (Modulation Transfer Function) performance remains the same. The wireless communication feature, and automatic x-ray detection function (known as 'SmartSwitch' in the US) also stay unaffected by the changes. The same acquisition workstation, FDX Console will continue to support FDR D-EVO FPD System (DR-ID600). FDX Console v9.0 or later will release the Dynamic Visualization II Image Processing Option for the FDX Console (DR-ID300CL of the DR-ID600).

	Subject/Modified Device **Dynamic Visualization II Image Processing Option for the FDX Console (DR-ID300CL of the DR-ID600)**	**Predicate Device** **FDX Console (DR-ID300CL) With Virtual Grid Software Option for the FDR D-EVO FPD system (DR-ID600) (K153464 cleared 4/8/2016)**
Indications for Use of the DR D-EVO FPD system DR-ID600	The Wireless/Wired FDR D-EVO flat panel detector system is intended to capture for display radiographic images of human anatomy. It is	The Wireless/Wired FDR D-EVO flat panel detector system is intended to capture for display radiographic images of human anatomy. It is

	Subject/Modified Device **Dynamic Visualization II Image Processing Option for the FDX Console (DR-ID300CL of the DR-ID600)**	**Predicate Device** **FDX Console (DR-ID300CL) With Virtual Grid Software Option for the FDR D-EVO FPD system (DR-ID600) (K153464 cleared 4/8/2016)**
(unchanged)	intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film /screen or CR systems may be used. The FDR D-EVO is not intended for mammography, fluoroscopy, tomography, and angiography applications.	intended for use in general projection radiographic applications including pediatric and neonatal exams wherever conventional film /screen or CR systems may be used. The FDR D-EVO is not intended for mammography, fluoroscopy, tomography, and angiography applications.
Indications for use for option	Dynamic Visualization II Image Processing is an optional software for the FDX Console, intended to provide optimized image quality over a wide range of patient thicknesses, especially for bariatric imaging. The device is not intended for mammography use.	The FDR D-EVO can be used with Virtual Grid Software, which is optional image processing software installed on Fujifilm's FDX Console. Virtual Grid Software can be used in lieu of an anti-scatter grid to improve image contrast in general radiographic images by reducing the effects of scatter radiation.
Option for	Same as Predicate	FDX Console of the Wireless/Wired FDR D-EVO flat panel detector system DR-ID600
Image Processing Characteristics		
Dynamic Visualization Algorithm	DV II uses a combination of EDR2 and MFP2	DV uses a combination of EDR and MFP
Exposure Data Recognizer Algorithm (EDR)	EDR2– to identify and optimize various anatomic structures in an acquired image prior to the subsequent application MFP2 processing, EDR2 uses a feature recognition method to identify direct x-ray, bone, tissue, and artificial object regions	EDR- uses the conventional histogram analysis method prior to the subsequent application MFP processing.
Frequency Noise Control (FNC)	Same as Predicate	Performs noise suppression
Multi objective Frequency Processing (MFP)	MFP2 performs Spatial Frequency Enhancement and Dynamic Range Control similar to that of MFP, but with two new lower frequency bands and automated Dynamic Range Control Features.	MFP performs Spatial Frequency Enhancement and Dynamic Range Control using six frequency bands and fixed Dynamic Range Control Features.
Gradation Processing (Gp)	Same	Performs global brightness and contrast adjustment following MFP processing.
Miscellaneous		
Available flat panel detectors	Same	Same
Detector Wireless Features	Same	Same

	Subject/Modified Device Dynamic Visualization II Image Processing Option for the FDX Console (DR-ID300CL of the DR-ID600)	Predicate Device FDX Console (DR-ID300CL) With Virtual Grid Software Option for the FDR D-EVO FPD system (DR-ID600) (K153464 cleared 4/8/2016)
Auto X-ray detection feature	Same	Same
Workstation Software Version	Same as Predicate	FDX Console Version 9.0
Minimum Basic Computer Configuration (as provided in US)	**Model**: HP ProDesk 600 G2 Series Small Form Factor PC **Processor**: Intel Core i5-6500 with 3.2GHz **RAM**: 4GB (4x1GB) **Hard Drive**: 500GB **CD/DVD**: Slim SuperMulti DVD drive **Display**: 17 " or 21" color (touchscreen optional) Monitor. **Accessories**: Keyboard, Mouse, Barcode scanner	**Model**: Mini Tower **Processor**: Core 2 Duo **RAM**: 2GB **Hard Drive**: 80GB **CD/DVD**: DVD drive **Display**: 17 " or 21" color (touchscreen optional) Monitor. **Accessories**: Keyboard, Mouse, Barcode scanner
Operating System	Windows 7 Professional 32-bit	Windows Vista/Windows 7 Professional 32-bit
Image Transfer	Same as Predicate	Standard network connectivity via DICOM protocol & via Fuji DMS Network

IV. SUBSTANTIAL EQUIVALENCE

The FDR D-EVO FPD System (DR-ID600) with the Dynamic Visualization II Image Processing Option is substantially equivalent to the following legally marketed device:

Legally Marketed Device	510(k) #	Clearance Date
FDR D-EVO Flat Panel Detector System (DR-ID600) with Improved Virtual Grid Software	K153464	4/8/2016

The FDX Console version 9.0 software was cleared with the FDR D-EVO FPD System (DR-ID600) in K153464. The FDR D-EVO's detector characteristics as well as other major features such as wireless communication and automatic x-ray detection function ('SmartSwitch') remain unchanged. The FDR D-EVO can be used with or without the Dynamic Visualization II Image Processing Option, and the improvements do not affect the intended use or alter the fundamental scientific technology of the legally marketed device. The only change between the predicate device and the proposed device of this submission is the addition of the Dynamic Visualization II Image Processing Option, which is an improvement of the Dynamic Visualization option available with the predicate device.

V. SUMMARY OF STUDIES

Non-clinical Performance Data: The conformity to the voluntary standards such as AAMI/ANSI ES60601-1, IEC 60601-1, IEC 60601-1-2, IEC 62304, IEC 62366, IEC 62494-1 and DICOM remains unaffected. As required by the risk analysis, all verification and validation activities related to the improvements made to the

Dynamic Visualization II Image Processing Option were performed and the results were satisfactory.

FUJIFILM conducted a comparative image quality evaluation between the predicate device Dynamic Visualization (DV) and the proposed modified device, Dynamic Visualization II (DV2). Raw clinical images were processed with the predicate image processing algorithms (DV), and then the raw images were processed using the proposed image processing algorithms (DV2). Randomized image pairs (DV vs. DV2) were then evaluated by three readers. Slightly more than half of the images were of bariatric patients. The results of the evaluation demonstrates that DV2 optimizes image quality for all patients, even when images of larger patients are processed using the proposed, modified device.

Clinical Performance Data: The changes do not require clinical studies. The substantial equivalence has been demonstrated by non-clinical studies.

VI. CONCLUSION

Based upon the supporting data summarized above, FMSU concludes the Dynamic Visualization II Image Processing Option offered with FDR D-EVO Flat Panel Detector System (DR-ID600) is as safe and effective as the legally marketed device K153464 and does not raise different questions of safety and effectiveness than K153464.