DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 16, 2017

FUJIFILM Medical Systems USA, Inc.
% Mr. Peter Altman
Regulatory and Quality Consultant
419 West Avenue
STAMFORD CT 06902

Re: K170451
Trade/Device Name: FDX Console (DR-ID300CL) Software
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 8, 2017
Received: February 15, 2017

Dear Mr. Altman:

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,

For

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)*

K170451

Device Name
FDX Console (DR-ID300CL) Software

Indications for Use *(Describe)*

The FDX Console is a workstation intended to associate digital (CR and/or DR) images with patient and exam information, apply image processing to facilitate diagnosis, display the image, and output the resulting image and exam data for further display, distribution, or archiving. The FDX Console is not for use in Mammography.

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)*

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510(k) Summary

FDX Console (DR-ID300CL) Software

Date: February 8, 2017

Submitter's Information:

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

Contact Person:

Name: Peter Altman
Title: Regulatory and Quality Consultant
Telephone: (203) 602-3576
Facsimile: (203) 602-3785

Identification of the Device:

Proprietary/Trade Name:	FDX Console (DR-ID300CL) Software
Classification Name:	Picture Archiving and Communications System
Regulations Number:	21 CFR 892.2050
Product Codes:	LLZ
Device Class:	Class II
Review Panel:	Radiology
Common Name:	Medical Image Processing Workstation or Acquisition Workstation

Identification of the Legally Marketed Predicate Devices:

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

2. Fuji Medical CR Console, K041990, cleared 8/6/2004

I. DEVICE DESCRIPTION

The FDX Console is used by a radiographer for viewing Digital Radiography (DR) and Computed Radiography (CR) images for final quality assurance (QA) checking and image processing and optimization prior to transferring the images to external devices such as a PACS or a printer. Furthermore, when connected to Fuji Image Readers via a network, the FDX Console is used to enter patient ID information, exposure information, and in the case of CR register Image Plate (IP) barcode numbers. The FDX Console is compatible with the ACR/NEMA DICOM Version 3.0 standard.

The four primary features of the FDX Console are patient identification, exam selection, image processing, and image transmission.

- Patient Identification feature: Patient demographics can be manually entered using a keyboard or captured from a RIS/HIS using DICOM Worklist Management. Also, a Touch screen monitor and barcode reader streamlines this data entry.
- Exam Selection feature: Select the patient, select the applicable exam, for CR barcode the Imaging Plate (IP), and touch Start to select the exam or use the DICOM Worklist Management feature with Auto Exam Select.
- Image Processing feature: DR and CR Images are processed, displayed and reviewed prior to image transfer.
- Image Transmission feature: Images are transferred to other medical imaging devices for softcopy viewing or storage devices for archiving or to a printer for hardcopy film output.

II. INDICATIONS FOR USE

The FDX Console is a workstation intended to associate digital (CR and/or DR) images with patient and exam information, apply image processing to facilitate diagnosis, display the image, and output the resulting image and exam data for further display, distribution, or archiving. The FDX Console is not for use in Mammography.

III. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The FDX Console is a software device based upon the predicate devices. The modifications implemented in Version 10.0 do not alter the technological characteristics of the predicates, i.e., software is installed on off-the-shelf computer hardware running Microsoft Windows operating systems.

IV. SUBSTANTIAL EQUIVALENCE

The FDX Console Version 10.0 Software is substantially equivalent to the following legally marketed device:

Legally Marketed Device	510(k) #	Clearance Date
Fuji Medical CR Console Model Flash IIP	K041990	8/6/2004
FDR D-EVO FPD System (DR-ID600) (includes the FDX Console Version 9.0 software)	K153464	4/8/2016

The CR Console has been chosen as the predicate device because it is the FDX Console's predecessor and therefore the general design including software, GUI, features, and capabilities are extremely similar. One of the major differences is that the FDX Console has the capability to acquire and process images from all Fujifilm digital radiography system whereas the CR Console was limited to Computed Radiography only.

The FDX Console version 9.0 software was cleared with the FDR D-EVO FPD System (DR-ID600) in K153464. It has exactly the same image processing software as the subject Version 10.0 device. The only differences are that FDX Console V10.0 will be able to use the Microsoft Windows 10 operating

system and that this submission introduces the SmartController and RemoteDesktop software capabilities allowing remote operation of the FDX Console. The following comparison applies:

	Subject Device **FDX Console (DR-ID300CL) Software**	**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)**	**Predicate Device** **Fuji CR Console (Flash IIP) (K041990 cleared 8/6/2004)**
Indications for Use	The FDX Console is a workstation intended to associate digital (CR and/or DR) images with patient and exam information, apply image processing to facilitate diagnosis, display the image, and output the resulting image and exam data for further display, distribution, or archiving. The FDX Console is not for use in Mammography.	The Wireless/Wired FDR D-EVO flat panel detector system is intended to capture for display radiographic images of human anatomy. It is 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.	The Fuji CR Console is a CR modality workstation intended to associate digital FCR images (except mammography images) with patient and exam information, apply image processing to facilitate diagnosis, display the image, and output the resulting image and exam data for further display, distribution, or archiving.
Indications for use for options	None.	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.	None.
Image Processing Characteristics			
Spatial Frequency Processing	Yes	Yes	Yes
Tonal Conversion	Yes	Yes	Yes
Dynamic Range Control Processing (DRC)	Yes	Yes	Yes
Tomographic Artifact Suppression Processing (TAS)	Yes	Yes	Yes
Gradation Processing	Yes	Yes	Yes
Multi-Objective Frequency Processing	Yes	Yes	Yes

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	Subject Device FDX Console (DR-ID300CL) Software	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)	Predicate Device Fuji CR Console (Flash IIP) (K041990 cleared 8/6/2004)
(MFP)			
Flexible Noise Control (FNC)	Yes	Yes	Yes
Grid Pattern Removal (GPR)	Yes	Yes	Yes
Image Automatic Composition Processing (Image Stitching)	Yes	Yes	Yes
CoRrection Filter (CRF)	Yes	Yes	No
Image processing without normalization	Yes	Yes	No
Tomosynthesis Option	Yes	Yes	No
Dual Energy Subtraction(DES) Option	Yes	Yes	No
Virtual Grid Option	Yes	Yes	No
Improved Virtual Grid Software (VG2)	Yes	Yes	No
Miscellaneous			
Workstation Software Version	10.0	9.0	A11
Transfer images to PACS	Yes	Yes	Yes
Enter Patient info manually	Yes	Yes	Yes
Enter Patient info from RIS	Yes	Yes	Yes
Select Exam	Yes	Yes	Yes
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	**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	**Model:**DELL Optiplex GX260 **Processor**: Pentium 4, 3.06GHz **Hard Drive**: 40GB **RAM**: 512MB **Display**: 17 " or 21" color (touchscreen optional) Monitor.

	Subject Device **FDX Console (DR-ID300CL) Software**	**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)**	**Predicate Device** **Fuji CR Console (Flash IIP) (K041990 cleared 8/6/2004)**
	optional) Monitor. **Accessories**: Keyboard, Mouse, Barcode scanner		
Operating System	Windows 10/Windows 7 Professional 32-bit	Windows Vista/Windows 7 Professional 32-bit	Windows 2000 Professional
Image Transfer	Same as Predicates	Standard network connectivity via DICOM protocol & via Fuji DMS Network	Standard network connectivity via DICOM protocol & via Fuji DMS Network
Remote Operation Capability of Console	SmartController and Remote Desktop	None	None

V. SUMMARY OF STUDIES

Non-clinical Performance Data: The FDX Console conforms to the following voluntary standards:

Standard	Title
DICOM, V3.0 2007	Digital Imaging and Communications in Medicine (DICOM)
IEC 62304: 2006	Medical Device Software – Software Life Cycle Processes
IEC 62366: 2014	Medical devices – Application of usability engineering to medical devices

As required by the risk analysis, all verification and validation activities related to the FDX Console were performed and the results were satisfactory. The verification and validation results are provided in the submission.

Clinical Performance Data: Clinical studies were not required as there is no change in image processing. The substantial equivalence has been demonstrated by non-clinical studies.

VI. CONCLUSION

Based upon the supporting data summarized above, we concluded the FDX Console (DR-ID300CL) Software is as safe and effective as the legally marketed devices K041990 andK153464 and does not raise different questions of safety and effectiveness than the predicate devices.