MAR 2 5 2014 K133972
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510(k) Summary

Date Prepared: December 18, 2013

Submitter's Information

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, Connecticut 06902
Telephone: (203) 602-3576
Facsimile: (203) 602-3785
Contact: Peter Altman

Device Name and Classification:

Product Name:	ASPIRE Cristalle
Model Number:	FDR MS-3500
Classification Name:	Full-Field Digital Mammography X-ray System
Classification Panel:	Radiology
CFR Section:	21 CFR 892.1715
Device Class:	Class II
Product Code:	MUE

Substantial Equivalence/Predicate Device:

FUJIFILM Aspire HD Plus (FDR MS-2500) (K121674)

The predicate and proposed devices have the same Indication For Use (IFU). Both devices generate digital mammographic images that are intended for screening and diagnosis of breast cancer and are intended for use in the same clinical applications as traditional screen-film mammography systems.

Both systems employ amorphous selenium digital x-ray detectors integrated into the gantry (stand) based x-ray systems. The Cristalle uses hexagonal pixels as compared to the square pixels of the HD Plus. The x-ray stands of the ASPIRE Cristalle and Aspire HD Plus are the same and the generators are extremely similar. The technological characteristics of the devices are similar as demonstrated by the comparison of imaging characteristics such as MTF, Noise Analysis, DQE, CNR, Phantom testing, etc. measured during non-clinical testing. Non-clinical testing was conducted in accordance with the FFDM 510(k) Guidance document covering Sensitometric Response, Spatial Resolution, Noise Analysis, Signal-to-Noise Ratio Transfer – DQE, Dynamic Range, Image Erasure and Fading, Repeated Exposure Test, AEC Performance, ACR MAP Phantom Testing, Contrast Detail Phantom Testing, Patient Radiation Dose Testing, and Breast Compression system Testing.

A clinical image attribute review was conducted by independent mammographic radiologists in accordance with the FFDM 510(k) Guidance document. The mammographic attributes of six (6) image sets of screening and diagnostic cases were reviewed for all exposure modes concluding that the ASPIRE Cristalle provides sufficiently acceptable image quality for mammographic use.

FUJIFILM MEDICAL SYSTEMS USA, INC.

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Description of the Device:

The ASPIRE Cristalle is an integrated FFDM system combining an X-ray system made by Fujifilm with Fujifilm's a-Se detector and Acquisition Workstation (AWS). The ASPIRE Cristalle creates digital mammography images by direct capture of x-ray energy using the a-Se detector. The detector is a Fujifilm design utilizing an a-Se photo-conversion layer with TFT Readout circuitry to acquire image data and transfer images to the AWS for automated post processing, technologist preview and QC, and subsequent transmission to hard copy printers, diagnostic workstations and archiving systems. The ASPIRE Cristalle provides powered compression and three AEC modes.

The ASPIRE Cristalle Acquisition Workstation (FDR 3000AWS) includes an off the shelf personal computer, the application software, Windows 7 Operating System, a 5megapixel portrait type monitor, and a hub. The hub transmits signals between the personal computer and control cabinet, and between the personal computer and exposure stand.

The AWS display primarily consists of three windows:

- Patient Information Input window
- Exposure Menu Selection window
- Study window.

The user may switch between these windows depending on the operation being performed. The X-ray control panel, which controls and observes the exposure stand, is always displayed in the lower part of each window. This allows setting the exposure conditions and confirming the radiation conditions on a single view.

Intended Use:

The Fujifilm Digital Mammography System, ASPIRE Cristalle (FDR MS-3500) generates full-field digital mammography images that can, as other full-field digital mammography systems, be used for screening and diagnosis of breast cancer and is intended for use in the same clinical applications as traditional screen-film mammography systems.

Safety Information:

The ASPIRE Cristalle introduces no new safety or efficacy issues other than those already identified with the predicate device. The results of the Hazard Analysis combined with the appropriate preventive measures taken indicate that the device is of moderate concern as per the May 11, 2005 issue of the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and is consistent with the level of concern indicated in the "Class II Special Controls Guidance Document: Full-Field Digital Mammography System" document issued on: November 5, 2010.

Conclusion:

This 510(k) premarket notification submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health. We conclude the subject devices to be as safe and effective as the predicate device based upon the clinical and non-clinical data summarized above.

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

March 25, 2014

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

Re: K133972
Trade/Device Name: ASPIRE Cristalle
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: II
Product Code: MUE
Dated: December 23, 2013
Received: December 26, 2013

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.

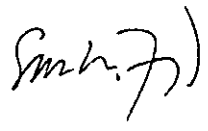
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 801and Part 809); 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 and Part 809), please contact 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/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 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133972

Device Name
ASPIRE Cristalle

Indications for Use *(Describe)*

The Fujifilm Digital Mammography System, ASPIRE Cristalle (FDR MS-3500) generates full-field digital mammography images that can, as other full-field digital mammography systems, be used for screening and diagnosis of breast cancer and is intended for use in the same clinical applications as traditional screen-film mammography systems.

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)*