FUJIFILM Medical Systems U.S.A., Inc.
% Jyh-Shyan Lin
Senior Manager, Regulatory, Quality and Clinical Affairs
419 West Avenue
STAMFORD CT 06902

October 27, 2017

Re: K173132
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: September 28, 2017
Received: September 29, 2017

Dear Jyh-Shyan Lin:

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 (DICE) 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 (DICE) 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173132

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

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510(k) Summary

Date Prepared: October 27, 2017

Submitter's Information:

FUJIFILM Medical Systems U.S.A., Inc.
419 West Avenue
Stamford, Connecticut 06902, U.S.A.
Telephone: (301) 251-1092
Contact: Jyh-Shyan Lin

Device Name and Classification:

Product Name:	ASPIRE Cristalle
Model Number:	FDR MS-3500
Classification Name:	Full-field digital mammography system
Classification Panel:	Radiology
CFR Section:	21 CFR 892.1715
Device Class:	Class II
Product Code:	MUE

Description of the Device:

The ASPIRE Cristalle (K133972) (FDR MS-3500) is an integrated FFDM system combining an X-ray system made by Fujifilm with Fujifilm's a-Se detector and FDR-AWS3000 acquisition workstation (AWS). The system creates digital mammography images by direct capture of x-ray energy using a detector of 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, technologists' preview and QC, and subsequent transmission to hard copy printers, diagnostic workstations and archiving systems. The ASPIRE Cristalle provides powered compression and AEC modes.

The subject of this premarket notification is a software upgrade to the predicate device. The hardware is unchanged. The software is unchanged with the exception that the subject device incorporates improved grayscale and frequency processing software named Dynamic Visualization II for Mammography (DVIIm) in the FDR-AWS3000 image acquisition software.

DVIIm image processing consists of EDR2m and MFP2 image processing.

- Exposure Data Recognition 2 for mammography (EDR2m) – the EDR2m algorithm analyzes image data and identifies various anatomic structures using a statistical estimation method as opposed to original EDR's histogram analysis method. EDR2m determines the parameters to optimize brightness and contrast of the image based on the analysis result.
- Multi-Object Frequency Processing 2 (MFP2) - MFP2 optimizes the brightness, contrast and sharpness of the image using parameters determined by the EDR2m processing. MFP2 uses additional low frequency tables and a combination of automatic and preset dynamic range control operations.

DVIIm takes full advantage of the wide range of image data acquired with the high sensitivity of Fujifilm's advanced detector technologies. DVIIm provides improved contrast and density stability throughout the entire exposure region and achieves improved visibility across a wide range of breast compositions including the presence of implants.

Intended Use (Unchanged from the predicate):

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.

Substantial Equivalence/Predicate Device:

FUJIFILM ASPIRE Cristalle (FDR MS-3500) (K133972)

The predicate and proposed devices have the same indications 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.

Testing and Performance Information:

Software: The development of DVIIm software includes the activities relating to the establishment of the software development plan (or plans) for definitely conducting software requirement analysis, architectural design, the detailed design, unit implementation and verification, software integration and integration testing, software system test, software release, software maintenance. Software verification and validation have been performed by the unit test, integration test, and system tests throughout the design verification phase and design validation phase. ASPIRE Cristalle maintains the confidentiality, integrity and availability in accordance with Section 6 of the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices; Guidance for Industry and Food and Drug Administration Staff (October 2, 2014).

Performance testing - bench: Applicable phantom testing results have been provided in accordance with the Phantom Testing in section 8. Physical Laboratory Testing of "Class II Special Controls Guidance Document: Full-Field Digital Mammography System" (March 27, 2012).

Performance testing - clinical: A clinical image attribute review was conducted by independent mammographic radiologists in accordance with the section 6 of "Class II Special Controls Guidance Document: Full-Field Digital Mammography System" (March 27, 2012) 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.

Safety Information:

The ASPIRE Cristalle with DVIIm image processing 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 "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (May 11, 2005) and is consistent with the level of concern indicated in the "Class II Special Controls Guidance Document: Full-Field Digital Mammography System" (March 27, 2012). The ASPIRE Cristalle meets the applicable basic safety and essential performance requirements for Medical Electrical Equipment, including IEC 60601-1, IEC 60601-1-2, , IEC 60601-1-3, IEC 60601-2-45, IEC 62304 and DICOM Version 3. The ASPIRE Cristalle labeling contains instructions for use and necessary cautions, warnings and notes to provide the safe and effective use of the device.

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.