FUJIFILM Corporation
% Jeffrey Wan
Manager, Regulatory Affairs
FUJIFLM Medical Systems U.S.A, Inc.
81 Hartwell Avenue, Suite 300
LEXINGTON MA 02421

May 27, 2022

Re: K212873
Trade/Device Name: Aspire Cristalle
Regulation Number: 21 CFR 892.1715
Regulation Name: Full-field digital mammography system
Regulatory Class: Class II
Product Code: MUE
Dated: April 27, 2022
Received: April 28, 2022

Dear Jeffrey Wan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT 8: Office of Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212873

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.

Dual energy procedures is an optional feature of the ASPIRE Cristalle that can capture images consecutively under two different tube voltage conditions during one compression, and then create and display a subtraction image of the two acquired images. This optional feature shall enable contrast enhanced breast imaging and is used as an adjunct following mammography. Dual energy procedures is not intended for primary screening or diagnosis.

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.

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FUJIFILM Medical Systems U.S.A., Inc.
81 Hartwell Avenue, Suite 300
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510(k) Summary

Date Prepared: September 8, 2021

Submitter's Information

Jeffrey Wan

Manager, Regulatory Affairs

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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

Predicate Device:

FUJIFILM ASPIRE Cristalle (FDR MS-3500) (K173132)

Reference Device:

GE SenoBright HD (K172404)

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.

Dual energy procedures is an optional feature of the ASPIRE Cristalle that can capture images consecutively under two different tube voltage conditions during one compression, and then create and display a subtraction image of the two acquired images. This optional feature shall enable contrast enhanced breast imaging and is used as an adjunct following mammography. Dual energy procedures is not intended for primary screening or diagnosis.

Description of the Device:

The ASPIRE Cristalle (K173132) (FDR MS-3500) 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 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.

This 510(k) submission introduces the optional feature of Dual energy procedures for the ASPIRE Cristalle. Dual energy procedures can capture images consecutively under two different tube voltage conditions during one compression, and then create and display a subtraction image of the two acquired images. This optional feature shall enable contrast enhanced breast imaging and is used as an adjunct following mammography. It should only be used with FDA approved contrast agents according to the manufacturer's instructions. The X-ray exposures must be performed after the contrast agent has diffused into the breast and before its washout, which is typically between 2 to 7 minutes after beginning of injection according to Clinical publications and/or the manufacturer's instructions. For the image acquisition in one direction, it takes about 25 seconds from the first X-ray exposure to the display of energy subtraction images.

Substantial Equivalence:

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. The proposed device has the optional item of Dual energy procedures and its IFU is added.

Both systems employ amorphous selenium digital x-ray detectors integrated into the gantry (stand) based x-ray systems and use hexagonal pixels. The x-ray stands and the generators of the predicate and proposed devices are the same. Both Acquisition Workstations (AWS) are based on the same application software. In the proposed device, Dual energy procedures to perform dual energy exposure and image subtraction can be available by software updates and use of Copper filter.

Comparative bench testing was conducted against the reference device SenoBright HD (K172404) to evaluate the Dual energy procedures. Based on the test results, it can be concluded that the proposed device is substantially equivalent to the predicate device.

Summary of Non-Clinical Testing:

The following non-clinical tests were conducted to evaluate the Dual energy procedures:

- Phantom Testing - ACR MAP
- Patient Radiation Dose
- Evaluation using the phantom dedicated to ES image
- Dose to the breast in AEC auto mode
- Non-uniformity（Brightness, SNR）
- Validity of AEC setting

- AEC repeatability
- Image uniformity
- Half Value Layer (HVL)
- Normalized Noise Power Spectrum (NNPS)
- Lag and Ghost

For all tests, the proposed device demonstrated substantial equivalence to the predicate device.

Summary of Clinical Testing:

The clinical evaluation was performed on 10 patient CEDM images by three (3) MQSA qualified expert mammographic radiologists. The results of this evaluation demonstrate that Dual energy procedures for the ASPIRE Cristalle produces images that are of acceptable quality for mammographic usage.

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: 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.

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 non-clinical data summarized above.