DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 29, 2017

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

Re: K171463
Trade/Device Name: ASPIRE Bellus II
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: August 25, 2017
Received: August 28, 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,

For

Robert A. 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)*
K171463

Device Name
ASPIRE Bellus II

Indications for Use *(Describe)*

ASPIRE Bellus II is medical imaging software that is intended to provide trained medical imaging professionals, including Physicians and Radiologists, with tools to aid them in reading, interpreting, reporting. This product accepts DICOM compliant medical images acquired from a variety of imaging devices including, MG, CT, PT, MR, CR, DX, and US, etc. This product also provides general 2D/3D viewing and general image processing, measurements, annotations, reporting, printing, storing, and general image administration tools, etc.

This product does not accept lossy compressed mammographic images, which should not be used for primary diagnostic interpretation. Display monitors connected to this produt for diagnostic interpretation of mammographic images must be approved for use in digital mammography. All images sent to or imported into this product must conform to regulatory requirements. Image quality must conform to applicable quality guidelines.

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.

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"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

Date Prepared:	August 25, 2017
Submitter's Information:	FUJIFILM Medical Systems U.S.A., Inc. 419 West Avenue Stamford, Connecticut 06902 Telephone: (301) 251-1092 Fax: (203) 602-3785 Contact: Jyh-Shyan Lin
Device Trade Name:	ASPIRE Bellus II
Device Common Names:	Picture Archiving and Communications System (PACS)
Device Clasification Name:	System, Image Processing, Radiological
Product Code:	LLZ
Regulation Number:	21 CFR 892.2050
Device Class:	Class II
Panel:	Radiology
Primary Predicate Device:	Synapse PACS 5.1.0 (K160108) FUJIFILM Medical Systems U.S.A., Inc.
Reference Predicate Device:	SenoIris (K160937) GE Healthcare

1. Description of the Device

ASPIRE Bellus II is medical application software with speedy image display and intelligent functions by image processing technologies. This application can support user to efficiently perform interpretation of examination images and make a diagnosis using various modality images and generate Mammography reports for diagnostic/screening purposes. ASPIRE Bellus II can receive various diagnostic images directly from image acquisition systems or PACS via network using DICOM protocol. Images are displayed on viewer monitors for doctors' review.

2. Indications for Use

ASPIRE Bellus II is medical imaging software that is intended to provide trained medical imaging professionals, including Physicians and Radiologists, with tools to aid them in reading, interpreting, reporting. This product accepts DICOM compliant medical images acquired from a variety of imaging devices including, MG, CT, PT, MR, CR, DX, and US, etc. This product also provides general 2D/3D viewing and general image processing, measurements, annotations, reporting, printing, storing, and general image administration tools, etc.

This product does not accept lossy compressed mammographic images, which should not be used for primary diagnostic interpretation. Display monitors connected to this product for diagnostic interpretation of mammographic images must be approved for use in digital mammography. All images sent to or imported into this product must conform to regulatory requirements. Image quality must conform to applicable quality guidelines.

3. Substantial Equivalence Comparison

ASPIRE Bellus II has the same intended use, similar labeling, and clinical application tools as those of the cleared primary predicate devices Synapse PACS 5.1.0 (K160108). The device features and technical characteristics comparison with predicates is shown as Table 1. Device Features and Technical Characteristics Comparison Matrix**,** and Table 2. Device Features and Technical Characteristics Comparison Matrix for functions for displaying Mammography Tomosynthesis images.

Table 1. Device Features and Technical Characteristics Comparison Matrix

Device Parameters	ASPIRE Bellus II (This submission)	Synapse PACS 5.1.0 (K160108) (Primary predicate)
Product availability	Provided as Software only	Provided as Software only
Operating Systems	Windows 7 Professional SP1 (64bit)/Windows 8.1/Windows 10	Windows XP/Vista/Windows7/Windows8.1

Device Parameters	ASPIRE Bellus II (This submission)	Synapse PACS 5.1.0 (K160108) (Primary predicate)
Web Browser	Internet Explorer Version: 11	Internet Explorer Version: 10 or 11 or Google Chrome
Database and file access method	Web based (http(s))	Web based (http(s))
Display of Digital Mammography Images	Yes	Yes
Process of Digital Mammography (Non-Processed or For Process) Images	Yes	Yes
On-demand access to database and images	Yes	Yes
Viewing study lists	Yes	Yes
Decompression for compressed images before display	Yes	Yes
Display images	Yes	Yes
Viewing report	Yes	Yes
Hanging Protocol	Yes	Yes
Spine labeling	Yes	Yes
Reference line display	Yes	Yes
Key images identification	Yes	Yes
Link multiple series	Yes	Yes
Measurement Tools	Yes	Yes
Annotation Tools	Yes	Yes
Standard Image Manipulation Tools (Window width/level, Zoom, Pan, etc.)	Yes	Yes
FCR IPSS for Fuji-CR-images	Yes	Yes
CT IPSS for CT images	Yes	Yes
Orthogonal and Oblique Multi Planar Reconstruction (MPR)	Yes	Yes
Maximum, Average, and Minimum Intensity Projection (MIP, MPVR, MinIP)	Yes	Yes
Independent Window/Level of upper and lower images in	Yes	Yes

Device Parameters	ASPIRE Bellus II (This submission)	Synapse PACS 5.1.0 (K160108) (Primary predicate)
Fusion Study		
Save Window/Level Preferences	Yes	Yes
Multi-Modal Fusion to include MR/PET/NM/and CT	Yes	Yes
Compare Current Study to previous study in Fusion View	Yes	Yes
Compare Current Study to Prior Study in Compare Mode	Yes	Yes
Image and Data Processing	Client side (Image Viewer)	Server side
Technology Platform (Client)	Platform Independent (Browser based UI)	Platform Independent (Browser based UI)
Technology Platform (Server)	Windows 7 Professional SP1 (64bit)/Windows 10 Pro (64bit)	Window server
System Security	Windows Authentication	Windows Authentication
Programming Language(s) (Synapse Client)	C++, C#, HTML, JavaScript	Javascript (TypeScript), HTML5, CSS

Table 2. Device Features and Technical Characteristics Comparison Matrix for functions for displaying Mammography Tomosynthesis images

Device Parameters	ASPIRE Bellus II (This submission)	SenoIris (K160937) (Reference predicate)
Support Multi-vendor Digital Breast Tomography	Yes	Yes
Drive multi-modality workflow from the PACS study list, including tomosynthesis	Yes	Yes
The ability to include tomosynthesis images in the hanging protocol	Yes	Yes
The display of synthetized 2D image	Yes	Yes

4. Safety Information

ASPIRE Bellus II introduces no new safety or efficacy issues other than those already indentified with the predicate device. The Risk Management and 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 Submission for Software Contained in Medical Devices.” The ASPIRE Bellus II labeling contains instructions for use and necessary cautions, warnings and notes to provide the safe and effective use of the device.

5. Testing and Performance Information

Nonclinical testing result:

The purpose of Software Development Process for ASPIRE Bellus II is to carry out 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. The main activities in software development process are described as follows.

- Software development plan
- Update of software development plan
- Software requirements analysis
- Software Architectural Design
- Software Detailed Design
- Software Unit Implementation and Verification
- Software Integration and Integration Testing
- Software System Testing
- Software Release

Clinical tests:

The subject of this 510(k) notification, ASPIRE Bellus II did not require clinical studies to support safety and effectiveness of the software.

Verification and Validation:

Software verification and validation have been performed by the following testing activities as defined in the procedure.

- Unit test: Code verification has covered unit level verification activities and no independent unit testing was planned.

- Integration test: According to the procedure, no specific integration test was planned, but the test cases for integration were included in the initial part of system test including system software build process, which integrates all software modules, and testing using the build results.
- System test: System test has been executed throughout the design verification phase and design validation phase.

Cybersecurity:

The confidentiality, integrity and availability are maintained by ASPIRE Bellus II 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)*.

ASPIRE Bellus II is connected through DICOM standard to medical devices such as CT, MR, CR, US, NM, PT, XA, etc. and to a PACS system storing data generated by these medical devices, and it retrieves image data via network communication based on the DICOM standard. Therefore ASPIRE Bellus II assure an adequate degree of protection for cybersecurity.

Performance standards:

- Digital Imaging and Communications in Medicine (DICOM) Set (PS 3.1 – 3.18).
- Medical device software – Software life cycle processes (IEC 62304 First edition 2006-05).
- Medical devices – Application of risk management to medical devices (14971 Second Edition 2007-03-01).

6. Conclusion

Performance tests were conducted to test the functionality of the subject device, ASPIRE Bellus II. Results of all conducted testing were acceptable in supporting the claim of substantial equivalence.