FUJIFILM Healthcare Corporation
% Dennis Domoracki
Senior Regulatory Affairs Specialist
FUJIFILM Healthcare Americas Corporation
81 Hartwell Avenue, Suite 300
LEXINGTON MA 02421

April 29, 2022

Re: K220295
Trade/Device Name: ARIETTA 50
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: January 27, 2022
Received: February 2, 2022

Dear Dennis Domoracki:

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,

Jessica Lamb, Ph.D.
Assistant Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*

K220295

Device Name
ARIETTA 50

Indications for Use *(Describe)*

This ARIETTA 50 is intended for use by trained personnel (doctor, sonographer, etc.) while in a healthcare facility for the diagnostic ultrasound evaluation of Fetal, Abdominal, Intra-operative (Spec.), Pediatric, Small Organ (Spec.), A Small Organ (Spec.), Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esoph. (non-Card.), Musculo-skel. (Convent.), Musculo-skel. (Superfic.), Other (Wound), Cardiac Adult, Cardiac Pediatric, Transesophageal (card.), Peripheral vessel, Other (Gynecological), clinical applications.
The Modes of Operation are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Power Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging).

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Section 5 510(k) Summary

Submitter Information

Submitter:	FUJIFILM Healthcare Corporation 2-1, Shintoyofuta, Kashiwa-Shi, Chiba, JP 277-0804
Contact:	Dennis Domoracki, Senior Regulatory Affairs Specialist
Telephone number:	(330)-425-1313 Ext:2792
E-mail:	dennis.domoracki@fujifilm.com
Date:	January 27, 2022

Contact Information (USA)

Address:	FUJIFILM Healthcare Americas Corporation 81 Hartwell Avenue, Suite 300 Lexington, MA 02421 USA

Subject Device Name

Trade/Proprietary Name:	ARIETTA 50
Regulation Number:	21 CFR 892.1550
Regulation Name:	Diagnostic Ultrasound System and Accessories
Product Code	90-IYN, 21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System 90-IYO, 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System 90-ITX, 21 CFR 892.1570 Diagnostic Ultrasonic Transducer
Class	II
Panel	Radiology

Predicate Device Name

Predicate Device(s):	ARIETTA 50 (K190248)
Regulation Number:	21 CFR 892.1550
Regulation Name:	Diagnostic Ultrasound System and Accessories
Product Code	90-IYN, 21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System 90-IYO, 21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System 90-ITX, 21 CFR 892.1570 Diagnostic Ultrasonic Transducer
Class	II
Panel	Radiology

Indications for Use

This ARIETTA 50 is intended for use by trained personnel (doctor, sonographer, etc.) while in a healthcare facility for the diagnostic ultrasound evaluation of Fetal, Abdominal, Intra-operative (Spec.), Pediatric, Small Organ (Spec.), A Small Organ (Spec.), Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esoph. (non-Card.), Musculo-skel. (Convent.), Musculo-skel. (Superfic.), Other (Wound), Cardiac Adult, Cardiac Pediatric, Transesophageal (card.), Peripheral vessel, Other (Gynecological), clinical applications.

The Modes of Operation are B mode, M mode, PW mode (Pulsed Wave Doppler), CW mode (Continuous Wave Doppler), Color Doppler, Power Doppler (Color Flow Angiography), TDI (Tissue Doppler Imaging).

FUJIFILM
Value from Innovation

Device Description

Function

The ARIETTA 50 is a multi-functional ultrasound diagnostic scanner in which Doppler, Color Flow Mapping, etc. are provided and all circuits related to image quality are fully digitalized. This device can be utilized with linear, convex, radial and phased array scan type probes for usage with a variety of clinical applications.

The ARIETTA 50 can be used for individual or combined display in the image display model listed below.

- B mode is a display mode in which the tomographic image is formed with plural ultrasound beams by the methods mentioned above. During the process of creating the tomographic image, adaptive filters (HI REZ) that modify the characteristics of each echo filter are used to produce a clear image.
- M mode is a display mode of ultrasound beams received sequentially and repeatedly on the screen from the same direction. It indicates these reflected echoes in one direction from the interior of the patient's body's on time-series scale.
- There are two types of D (Doppler) mode: PW Doppler mode and CW Doppler mode. PW Doppler mode displays bloodstream information consecutively at a sample point that is detected by pulsed Doppler sonography. CW Doppler mode displays bloodstream information continuously in the single-direction ultrasound beam that is detected by the CW Doppler method.
- Color Doppler mode receives ultrasound from the same direction and detects any changes that occur over time to identify three types of bloodstream information: its direction, its speed, and its inconsistency. The mode then colors that information and displays it as an overlay on B mode or M mode. Color Flow Mode, Power Doppler Mode, High-Resolution Power Doppler (eFlow) Mode can be used with this instrument according to need.

The 4 methods of electronic scanning are as follows.

- Linear Scanning Method:

  By this method, the ultrasound beam from the ultrasound probe is emitted in a straight line (linearly) and draws a tomographic image of the test subject.
- Convex Scanning Method:

  By this method, the ultrasound beam from the ultrasound probe is emitted radially and draws a tomographic image of the test subject.
- Sector Scanning Method:

  By this method, the ultrasound beam from the ultrasound probe is emitted in a fan shape (sector) and draws a tomographic image of the test subject.
- Trapezoidal Scanning Method:

  By this method, the ultrasound beam from the ultrasound probe is emitted radially without regard to the form of the probe head and draws a tomographic image of the patient.

Scientific Concepts

The principle of operation of ultrasound imaging involves generation of an ultrasound wave pulses with an electric signal applied to a transducer, direction of the resulting ultrasound wave into the tissue of the body, and reception and analysis of the echoes reflected back to the same or an adjacent transducer from the various tissues along the path of the ultrasound wave. The ultrasound waves comprising a beam travel in as straight line in homogeneous media. When an ultrasound wave reaches an interface between two media of different impedances, a portion of the beam energy may pass through the boundary (transmission), and a portion may be reflected. The direction of propagation of the transmitted beam is determined by the angle of incidence of the incident beam upon the boundary, and differences (if any) in the speed of sound in the two media. The direction of reflection is determined solely by the angle of incidence upon the boundary. The relative strength of the reflected wave depends upon the differences in the impedances between the two media. Reflection at a boundary between soft tissue and bone, as an example, involves a large impedance difference, and results in a relatively strong reflected echo. Reflection at a boundary between two soft tissue-types with a relatively small impedance difference, on the other hand, results in a relatively weak reflected echo.

Physical and Performance Characteristics

Analysis confirms the performance characteristics of the ARIETTA 50 are comparable to the predicate device and support our conclusion that the subject system is substantially equivalent.

Performance Comparison

No new hazards were identified with the ARIETTA 50. The subject device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform to applicable medical device safety standards.

Testing Type	Rationale Analysis
Performance Testing - Bench	FUJIFILM Healthcare Corporation judged that ARIETTA 50 is substantially equivalent to the predicate.
Performance Testing - Clinical	None required

The analysis confirms the performance characteristics of the ARIETTA 50 are comparable to the predicate device and support our conclusion that the subject device is substantially equivalent.

FUJIFILM
Value from Innovation

Device Technological Characteristics

The technological characteristics differences between the ARIETTA 50 and the predicate device ARIETTA 50 (K190248) are:

- Physical characteristics of the system

There are no significant differences in appearance, weight, size, hardware, transmit/receive parameters, modes of operation, and features from the predicate device.

ARIETTA 50 Subject Device	ARIETTA 50 Predicate Device (K190248)
	

- Probes

Probe	Previous Clearance
C22K	ARIETTA 65 (K202422)
C22P	ARIETTA 65 (K202422)
C251	ARIETTA 65 (K202422)
C35	ARIETTA 65 (K202422)
C41B	ARIETTA 65 (K202422)
C41L47RP	ARIETTA 65 (K202422)
C41RP	ARIETTA 65 (K202422)
C41V	ARIETTA 65 (K202422)
C42K	ARIETTA 65 (K202422)
CC41R	ARIETTA 65 (K202422)
L64	ARIETTA 65 (K202422)
S31	ARIETTA 65 (K202422)
VC35	ARIETTA 65 (K202422)
VC41V	ARIETTA 65 (K202422)

- New Features
  - Real-time 3D
  - 4Dshading

FUJIFILM
Value from Innovation

Substantial Equivalence

A summary decision was based on a thorough analysis and comparison of the functions, scientific concepts, physical and performance characteristics, performance comparison and technological characteristics.

Probes
The 13 additional probes for the system meet user requirements in regards to indications for use and have no effect on the safety and effectiveness of the device. These probes have been cleared by previous 510(k) submissions. See Probe Comparison Chart below.
Features
The ARIETTA 50 has 2 additional features (Real-time 3D, 4Dshading). However, these features where cleared in previous 510(k) submissions (ARIETTA 65, K202422). Therefore, FUJIFILM judges that the ARIETTA 50 has no additional issues with safety and effectiveness.

Based on analysis of the above-mentioned comparison, FUJIFILM Healthcare Corporation has judged the subject device to have the equivalent safety and effectiveness of the predicate device.

Summary of Non-Clinical Testing

The ARIETTA 50 V3.0 system is in conformance with the applicable parts of the following standards:

- AAMI ANSI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
  Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
- IEC 60601-2-37 Edition 2.1 2015
  Medical electrical equipment - part 2-37: particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment. (Radiology)
- IEC 60601-1-2 Edition 4.0 2014-02
  Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests. (General II (ES/EMC))
- AAMI I ANSI I ISO 10993-1:2009/(R)2013
  Biological evaluation of medical devices - part I: evaluation and testing within a risk management process. (Biocompatibility)
- AAMI I ANSI I ISO 10993-5:2009/(R)2014
  Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity. (Biocompatibility)
- AAMI I ANSI I ISO I 0993-10: 2002 + am1 2006
  Biological evaluation of medical devices - part I 0: tests for irritation and skin sensitization. (Biocompatibility)

Summary of Clinical Testing

Clinical testing was not required.

Conclusions

It is the opinion of FUJIFILM Healthcare Corporation. that the ARIETTA 50 Ultrasound Diagnostic scanner and transducers is substantially equivalent to the predicate devices. The subject device software features, intended use, materials, and diagnostic capabilities have been taken from the predicate devices. In addition, we have concluded that the subject device and predicate devices are substantially equivalent with respect to safety, effectiveness, and functionality.