



November 20, 2023

Fujifilm Healthcare Americas Corporation  
% Chaitrali Kulkarni  
Sr. Regulatory Affairs Specialist  
2-1, Shintoyofuta  
Kashiwa-shi Chiba  
JAPAN

Re: K231941

Trade/Device Name: ARIETTA x10  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic Pulsed Doppler Imaging System  
Regulatory Class: Class II  
Product Code: IYN  
Dated: October 17, 2023  
Received: October 17, 2023

Dear Chaitrali Kulkarni:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Yanna S. Kang -S**

Yanna Kang, Ph.D.

Assistant Director

Mammography and Ultrasound Team

DHT8C: Division of Radiological Imaging  
and Radiation Therapy Devices

OHT8: Office of Radiological Health

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

Submission Number (if known)

K231941

Device Name

ARIETTA x10

Indications for Use (Describe)

The ARIETTA x10 is intended for use by trained personnel (doctor, Sonographer, etc.) while in a healthcare facility for the diagnostic ultrasound evaluation of Fetal, Abdominal, Intraoperative (Specify\*1), Intra-operative (Neurosurgery), Laparoscopic, Pediatric, Small Organ (Specify\*2), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Transesophageal (non-Cardiac), Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Other (Specify - Gynecological), Other (Specify - Wound), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (Cardiac), Peripheral vessel, 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), 3D Imaging, 4D Imaging.

\*1. Includes imaging for organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

\*2. Includes thyroid, parathyroid, breast, scrotum, penis.

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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## 510(k) Summary

**K231941**

### Submitter Information

Submitter:	FUJIFILM Healthcare Corporation 2-1, Shintoyofuta, Kashiwa shi Chiba, Japan
Contact:	Chaitrali Kulkarni
Telephone number:	704-517-4886
E-mail:	<a href="mailto:chaitrali.kulkarni@fujifilm.com">chaitrali.kulkarni@fujifilm.com</a>
Date:	November 20, 2023

### Subject Device Name

Trade/Proprietary Name:	ARIETTA x10
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
Class	II
Panel	Radiology

### Predicate Device Name

Predicate Device(s):	ALOKA ARIETTA 850 (K183456)
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

### Reference Device(s)

Predicate Device(s):	ARIETTA 65 (K181376)
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(s):	ALOKA ARIETTA 850 (K202422)
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(s):	ALOKA ARIETTA 850 (K173739)
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(s):	ARIETTA 750 (K191233)
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

## Device Intended Use

The ARIETTA x10 is intended for use by trained personnel (doctor, Sonographer, etc.) while in a healthcare facility for the diagnostic ultrasound evaluation of Fetal, Abdominal, Intraoperative (Specify\*1), Intra-operative (Neurosurgery), Laparoscopic, Pediatric, Small Organ (Specify\*2), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Transesophageal (non-Cardiac), Musculo-skeletal (Conventional), Musculo-skeletal (Superficial), Other (Specify - Gynecological), Other (Specify - Wound), Cardiac Adult, Cardiac Pediatric, Trans-esophageal (Cardiac), Peripheral vessel, 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), 3D Imaging, 4D Imaging.

\*1. Includes imaging for organs and structures exposed during surgery (excluding neurosurgery and laparoscopic procedures).

\*2. Includes thyroid, parathyroid, breast, scrotum, penis.

## Device Description

### *Function*

ARIETTA x10 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 and phased array scan type probes for usage with a variety of clinical applications.

The ARIETTA x10 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 echoed. The workstation is based on current PC technology using the Windows™ operating system.

**Physical and Performance Characteristics**

Analysis confirms the performance characteristics of the ARIETTA x10 are comparable to the predicate device and support our conclusion that the subject system is substantially equivalent.

**Performance Comparison**

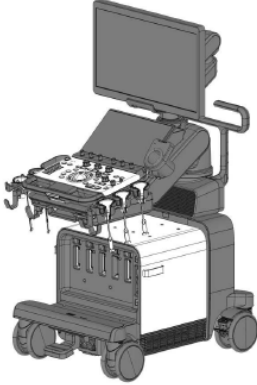

No new hazards were identified with the ARIETTA x10. The subject device and its transducers have been evaluated for acoustic output, biocompatibility, cleaning & disinfection effectiveness, electromagnetic compatibility, as well as electrical and mechanical safety, and have been found to conform to applicable medical device safety standards.

Testing Type	Rationale Analysis
Performance Testing - Bench	ARIETTA x10 is substantially equivalent to the predicate.
Performance Testing - Clinical	None required

The analysis confirms the performance characteristics of the ARIETTA x10 are comparable to the predicate device and support our conclusion that the subject device is substantially equivalent

## Device Technological Characteristics

The technological characteristics differences between the ARIETTA x10 and the predicate device ALOKA ARIETTA 850 (K183456) are:

ITEM	ARIETTA x10 Subject Device	ALOKA ARIETTA 850 (K183456) Predicate Device
<b>System Configuration</b>		
Dimensions		
	535mm (width)	550mm (width)
	954mm (depth)	960mm (depth)
	1245-1725mm (height)	1250-1650mm (height)
Weight	Approximate: .155kg	Approximate: 150kg
Monitor	22 inch OLED	22 inch OLED / 23inch LCD
Probe Connections	5 probes w/option	4 probes w/option
Track	3	3

## 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.

Item	Overall Rationale Analysis
<b>System Configuration</b>	The differences in appearances, weight, size, and hardware have no effect on the safety and effectiveness of the device.
<b>Probes</b>	The 5 new probes (C421, C23RV, CC41R2, CL4416R1, L31KP) for the system and the changed probe, S3ESEL, meet user requirements in regards to indications for use and have no effect on the safety and effectiveness of the device.
<b>Transmit/Receive Parameters</b>	The differences in transmitter and receiver specifications have been determined to have no effect on the safety and effectiveness of the device.
<b>Modes of Operation</b>	The differences in the available display modes have no effect on the safety and effectiveness of the device.

Item	Overall Rationale Analysis
Features (All)	The Built-in Battery has been previously cleared. (K181376)

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

## Summary of Non-Clinical Testing

The ARIETTA x10 V1.0 system is in conformance with the applicable parts of the following standards:

- ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]  
Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)]
- 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
- IEC 60601-1-2 Edition 4.1 2020-09  
Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ANSI AAMI ISO 10993-1: 2018  
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ANSI AAMI ISO 10993-5:2009/(R)2014  
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ANSI AAMI ISO 10993-10:2010/(R)2014  
Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION  
Medical device software - Software life cycle processes
- FDA Guidance “Marketing Clearance of Diagnostic Ultrasound Systems and Transducers” issued February 2023

## Summary of Clinical Testing

Clinical testing was not required.

## Conclusions

It is the opinion of FUJIFILM Healthcare Corporation that the ARIETTA x10 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 the primary predicate device is substantially equivalent with respect to safety, effectiveness, and functionality.