Hitachi Healthcare Americas
℅ Mr. Aaron Pierce
Director, RA/QA
1959 Summit Commerce Park
TWINSBURG OH 44087

November 4, 2020

Re: K202422
Trade/Device Name: Arietta 65
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: August 14, 2020
Received: August 24, 2020

Dear Mr. Pierce:

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

Thalia T Mills, Ph.D.
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)*
K202422

Device Name
ARIETTA 65

Indications for Use *(Describe)*
This ARIETTA 65 is intended for use in a Healthcare facility (hospital, private medical office, etc.) by Healthcare trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Fetal, Abdominal, Intra-operative (Spec.), Intra-operative (Neuro.), Laparoscopic, Pediatric, Small Organ (Spec.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esoph. (non-Card.), Musculo-skel. (Convent.), Musculoskel. (Superfic.), Other (spec.) - Gynecological, Other (spec.) - Wound, Cardiac Adult, Cardiac Pediatric, Trans-esophageal (card.), 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.

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 K202422

Submitter Information

Submitter:	Hitachi Healthcare Americas 1959 Summit Commerce Park Twinsburg, Ohio 44087-2371
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E-mail:	piercea@hitachihealthcare.com
Date:	January 18, 2019

Subject Device Name

Trade/Proprietary Name:	ARIETTA 65
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

Main Predicate Device:	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
Reference Devices	• NOBLUS™ Ultrasound Diagnostic System (K160559) • ALOKA ARIETTA 850 (K183456)

Indications for Use

This ARIETTA 65 is intended for use in a Healthcare facility (hospital, private medical office, etc.) by Healthcare trained personnel (doctor, sonographer, etc.) for the diagnostic ultrasound evaluation of Fetal, Abdominal, Intra-operative (Spec.), Intra-operative (Neuro.), Laparoscopic, Pediatric, Small Organ (Spec.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Trans-esoph. (non-Card.), Musculo-skel. (Convent.), Musculoskel. (Superfic.), Other (spec.) - Gynecological, Other (spec.) - Wound, Cardiac Adult, Cardiac Pediatric, Trans-esophageal (card.), 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.

Device Description

Function

The ARIETTA 65 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 65 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 65 are comparable to the predicate device and support our conclusion that the subject system is substantially equivalent.

Performance Comparison

As part of our design validation performance comparison analysis was conducted to demonstrate continued conformance with a special control or recognized standard.

No new hazards were identified with the ARIETTA 65. 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
Validation Testing - Bench	Hitachi judged that ARIETTA 65 is substantially equivalent to the predicate.
Validation Testing - Clinical	None required

The analysis confirms the performance characteristics of the ARIETTA 65 are comparable to the predicate device and support our conclusion that the subject device is substantially equivalent.

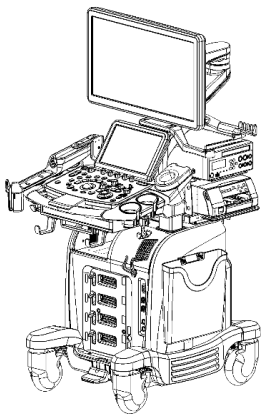
Device Technological Characteristics

The technological characteristics differences between the ARIETTA 65 and the predicate device ALOKA ARIETTA 850 (K173739) are:

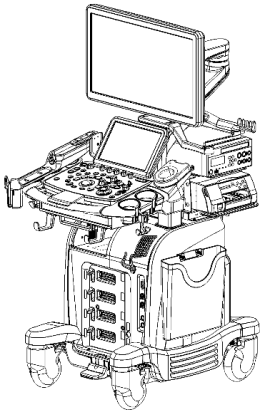
- Physical characteristics of the system

There are differences in appearance, weight, size, and hardware from the predicate device.

ARIETTA 65



ARIETTA 65 (K181376)



- Additional new probes

As compared to the predicate device, there are 27 additional probes available with the ARIETTA 65 that were previously cleared:

New Probe	Predicate Probe	Previously Cleared Device
C35	None	ARIETTA 60 (K140443)
C41	None	ARIETTA 60 (K140443)
C42	None	ARIETTA 60 (K140443)
C22P	None	ARIETTA 60 (K140443)
C25P	None	ARIETTA 60 (K140443)
C41V	None	Noblus (K160559)
C41RP	None	ARIETTA 60 (K140443)
C41B	None	ARIETTA 60 (K140443)
CC41R	None	ARIETTA 60 (K140443)
C22K	None	ARIETTA 60 (K140443)
C42K	None	ARIETTA 60 (K140443)
C42T	None	ARIETTA 60 (K140443)
R41R	None	ARIETTA 60 (K140443)
L34	None	ARIETTA 60 (K140443)
L441	None	ARIETTA 60 (K140443)
L64	None	ARIETTA 60 (K140443)
L43K	None	ARIETTA Precision (K163505)
L44K	None	ARIETTA Precision (K163505)
L46K1	None	ARIETTA Precision (K163505)
L51K	None	ARIETTA Precision (K163505)
L53K	None	ARIETTA Precision (K163505)
L44LA	None	ARIETTA Precision (K163505)
S31	None	ARIETTA 60 (K140443)
S31KP	None	ARIETTA 60 (K140443)
VC35	None	ALOKA ARIETTA 850 (K183456)
VC41V	None	ARIETTA 60 (K140443)
C41L47RP	None	ARIETTA 60 (K140443)

- Features

Shear Wave Measurement, Freehand 3D, Real-time 3D, and Marking Assist Display are additional features that were previously cleared (ALOKA ARIETTA 850, K183456) and have no effect on the safety and effectiveness of the device and in regards to indications for use.

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
System Configuration	
There are not differences between the predicate device and the subject device in regards to system configuration.	
Probes	
The 27 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. All probes have been previously cleared as indicated in Probe Comparison Chart below.	
Transmit/Receive Parameters	
There are no differences between the predicate device and the subject device in regards to transmit/receive parameters.	
Modes of Operation	
The reference frequency has been revised but will have no effect on the safety and effectiveness of the device.	
Features	
The Shear Wave Measurement, Freehand 3D, Real-time 3D, and Marking Assist Display are additional features that were previously cleared in Aloka Arietta 850, k183456, and have no effect on the safety and effectiveness of the device and in regards to indications for use.	

Based on analysis of the above-mentioned comparison, Hitachi has judged the ARIETTA 65 to have the equivalent safety and effectiveness of the predicate device, ARIETTA 65 (K181376).

Summary of Non-Clinical Testing

The ARIETTA 65 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/(B) 2013
  Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process [Including Technical Corrigendum 1 (2010)]
- AAMI I ANSI I ISO 10993- 5:2009/(R) 2014
  Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ANSI AAMI ISO10993-10: 2002 + am1 2006
  Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Summary of Clinical Testing

Clinical testing was not required.

Conclusions

It is the opinion of Hitachi, Ltd. that the ARIETTA 65 ultrasound diagnostic scanner and transducers are substantially equivalent to the predicate device. The subject device software features, intended use, materials, and diagnostic capabilities have been taken from the predicate device. In addition, we have concluded that the subject device and predicate device is substantially equivalent with respect to safety, effectiveness, and functionality.