September 12, 2022

Kolo Medical (Suzhou) Co., Ltd
℅ Mike Su
RA Manager
Room 303-305 and 504, Building A5, No. 218 Xinghu Street
Suzhou, Jiangsu 215123
CHINA

Re: K221568
Trade/Device Name: Evolution XHD Series Ultrasound Diagnostic Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, ITX, IYO
Dated: August 12, 2022
Received: August 15, 2022

Dear Mike Su:

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,

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

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)*

K221568

Device Name
Evolution XHD Series Ultrasound Diagnostic System

Indications for Use *(Describe)*

The Evolution XHD Series Ultrasound Diagnostic System is a high frequency general-purpose ultrasound system. It is intended for use by, or under the direction of a qualified and trained physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The device is intended for use in a hospital environment.

The systems support the following clinical applications:
The Evolution XHD Series Diagnostic Ultrasound System is applicable for adult and pediatric. It is intended for use in Pediatric, Small parts (breast, thyroid, testicles, prostate), Peripheral vessel, Dermatological, Musculoskeletal (conventional), Musculoskeletal (superficial).

Modes of operation include: B Mode, Color Doppler, Power Doppler, PW Doppler, Combined modes: B+Color Doppler, B+Power Doppler, B+PW Doppler.

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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510(k) Summary
K221568

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date Prepared:	Aug 11, 2022
Manufacturer:	Kolo Medical (Suzhou) Co., Ltd Room 303-305 and 504, Building A5, No. 218 Xinghu Street, Biobay, Industry Park, China (Jiangsu) Pilot Free Trade Zone, Suzhou, 215123 Jiangsu, P.R. China
Contact Person:	Mike SU Regulatory Affair Mananger Kolo Medical (Suzhou) Co., Ltd Tel: (+86) 13862426770 mike@kolomedical.com

Identification of the Device:

Proprietary/Trade Name:	KOLO Evolution XHD Series
Classification Name:	Ultrasound Diagnostic System
Regulatory Number:	21 CFR 892.1550, 1560, 1570
Product Code:	IYN, ITX, IYO
Device Class:	Class II
Review Panel:	Radiology

Identification of the Legally Marketed Predicate Device:

Trade Name:	FUJIFILM SonoSite Vevo MD Imaging System
Classification Name:	Ultrasound Diagnostic System
Regulatory Number:	21 CFR 892.1550, 1560, 1570
Product Code:	IYN, ITX, IYO
Device Class:	Class II
Review Panel:	Radiology
Submitter/510(k) Holder:	FUJIFILM SonoSite, Inc.
Clearance:	K190476 (cleared March 15, 2019)

Device Description:

The Evolution XHD Series device is a high frequency general purpose, software controlled, diagnostic imaging system used to acquire and display high-resolution, real-time ultrasound data. The Evolution XHD Series device is comprised of transducers responsible for ultrasound signal generation, and a main unit that controls the transducers, processes the acoustic data, and processes and displays images.

The main unit is a laptop ultrasound console with integrated keyboard, a color video LCD type display and operates from an integrated battery or separate power supply/charger.

Evolution XHD Ultrasound Diagnostic System integrated 4 linear probe transducers: L22-8 K2, L28-12K2, L38-22K2, L62-38K2.

Intend use of each probe on Evolution XHD Ultrasound Diagnostic System listed as below table:

Probe Model	Probe Type	Intended Use	Applicable Body Part
L22-8K2	Linear	Pediatric, Dermatological, Small parts (breast, thyroid, testicles, prostate), musculoskeletal (conventional), musculoskeletal (superficial), Peripheral vessels	Surface
L28-12K2	Linear	Pediatric, Dermatological, Small parts (breast, thyroid, testicles, prostate), musculoskeletal (superficial), Peripheral vessels	Surface

L38-22K2	Linear	Pediatric, Dermatological, musculoskeletal (superficial), Peripheral vessels	Surface
L62-38K2	Linear	Pediatric, Dermatological	Surface

Evolution XHD Ultrasound Diagnostic System has 6 models: Evolution XHD 80, Evolution XHD 70, Evolution XHD 65, Evolution XHD 60, Evolution XHD 55, Evolution XHD 50. The different models of ultrasonic diagnosis system as below table:

Model	Probe	Mode	SW Function of Auto Optimize (one-key optimize)
Evolution XHD 50	L22-8K2+ L38-22K2+ L62-38K2	B/C/PW	Not support
Evolution XHD 55	L22-8K2+ L38-22K2+ L62-38K2	B/C/PW/Power	Not support
Evolution XHD 60	L22-8K2+ L28-12K2+ L38-22K2+ L62-38K2	B/C/PW	Not support
Evolution XHD 65	L22-8K2+ L28-12K2+ L38-22K2+ L62-38K2	B/C/PW/Power	Not support
Evolution XHD 70	L22-8K2+ L28-12K2+ L38-22K2+ L62-38K2	B/C/PW	Support
Evolution XHD 80	L22-8K2+ L28-12K2+ L38-22K2+ L62-38K2	B/C/PW/ Power	Support

Indications for Use:

The Evolution XHD Series Ultrasound Diagnostic System is a high frequency general-purpose ultrasound system. It is intended for use by, or under the direction of a qualified and trained physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The device is intended for use in a hospital environment.

The systems support the following clinical applications:

The Evolution XHD Series Diagnostic Ultrasound System is applicable for adult and pediatric. It is intended for use in Pediatric, Small parts (breast, thyroid, testicles, prostate), Peripheral vessel, Dermatological, Musculoskeletal (conventional), Musculoskeletal (superficial).

Modes of operation include: B Mode, Color Doppler, Power Doppler, PW Doppler, Combined modes: B+Color Doppler, B+Power Doppler, B+PW Doppler.

Comparison with Predicate Device:

The Evolution XHD series Ultrasound Diagnostic System and its predicate device, the FUJIFILM SonoSite Vevo MD Imaging System (K190476), have the same intended use, and similar physical characteristics.

Description	**Subject Device** KOLO Evolution XHD Ultrasound Diagnostic System	**Predicate Device** FUJIFILM SonoSite Vevo MD Imaging System **(K190476)**
Intended Use	Diagnostic ultrasound imaging, measurement, display and analysis of the human body and fluid.	Diagnostic ultrasound imaging or fluid flow analysis of the human body.
Indications for use	Specific clinical applications and exam types include: Pediatric, Small parts(breast, thyroid, testicles, prostate), Peripheral vessel, Dermatological, Musculoskeletal (conventional), Musculoskeletal (superficial).	Specific clinical applications and exam types include: Abdominal Dermatological Musculoskeletal (conventional) Musculoskeletal (superficial) Neonatal Cephalic Ophthalmic Pediatric Peripheral vessel Small Organ (breast, thyroid, testicles, prostate)
User	Qualified and trained physician	Qualified and trained physician
Environment	Hospital environment	Hospital environment
Transducer Types Available	Linear Array	Linear Array
Transducer Center Frequency	15-50MHz	15-49MHz
Transducer Element	256-element linear array detector	256-element linear array detector
Modes of Operation	B Mode, Color Doppler, Power Doppler, PW Doppler	2D Mode, Color Doppler, M-Mode, Power Doppler, PW Doppler
DICOM	DICOM 3.0	DICOM 3.0

Description	**Subject Device** KOLO Evolution XHD Ultrasound Diagnostic System	**Predicate Device** FUJIFILM SonoSite Vevo MD Imaging System **(K190476)**
#Transmit Channels	128 digital channels	64 digital channels
#Receive Channels	64 digital channels	64 digital channels
Patient Contact Materials	Material meet ISO 10993-1 and FDA guidance	Material meet ISO 10993-1 and FDA guidance
Acoustic Output within FDA guidelines	Track 3;	Track 3;
general safety and effectiveness information	ANSI/AAMI ES60601-1 IEC60601-2-37 IEC60601-1-2 ISO 10993-1	ANSI/AAMI ES60601-1 IEC60601-2-37 IEC60601-1-2 ISO 10993-1
Labeling	Conforms to 21 CFR Part 801	Conforms to 21 CFR Part 801
SW functions	• Zoom, • Dual Display • Annotation • Bodymark, • Report • DICOM	• Zoom • Dual Window • Annotation • Bodymark, • Report • DICOM.
Measurement	• Distance • Area • Volume • Angle • Length trace • Curve	• Linear • Area • Volume • Angle • Traced Distance • Curve • IMT

Technology:
The Evolution XHD Series employs the same fundamental scientific technology as its predicated device.

Determination of substantial equivalence:
The Proposed Evolution XHD Series system are substantially equivalent to the predicate the FUJIFILM SonoSite Vevo MD Imaging System (K190476) with regards to intended use, indication for use, image capabilities, technological characteristics, image mode, and safety effectiveness.
The following is an overview of the differences between the proposed Evolution XHD Series and its predicate device.
Comparison Analysis:
Note 1:
Indication for use:
The Indication for use of subject device does not support Abdominal, Neonatal Cephalic, Ophthalmic. It is less than Predicate device. They can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.
Note 2:
The subject device does not support M mode. The mode of operation is less than Predicate device. They can be considered Substantially Equivalent in safety and effectiveness, and no new risk is raised, so the SE is not affected.
Note 3:
Transmit Channels: The subject device is 128 channels, and predicted device is 64 channels. The performance is better on image quality of subject device as the channels more than predicted one.

Summary of Non-clinical test:
The Evolution XHD Series were evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and have been found to comply with applicable medical device safety standard, The Evolution XHD Series complies with voluntary standards:

1. AAMI/ANSI ES60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, 2005/A2:2012
2. IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Disturbance – Requirements and tests, 2014
3. IEC 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic

medical diagnostic and monitoring equipment, Ed2.1, 2015
4. ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process, 2018
5. ISO 10993-5 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity
6. ISO 10993-10 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization
7. IEC62359, Ultrasonics-Field characterization- Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017.
8. ISO 14971 Medical Devices - Applications of Risk Management to Medical Devices, 2019
9. NEMA PS3.1-3.20, Digital Imaging and Communications in Medicine (DICOM) Set.(radiology), 2016.
10. IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability
11. IEC 62366 Consolidated Version Medical Devices - Application of Usability Engineering to Medical Devices
12. IEC 62304 Medical Device Software - Software Life Cycle Processes

The following quality assurance measures are applied to the development of the system:

Risk Management
Requirement review and Design reviews
Integration testing (system verification)
Performance testing (Verification)
Safety testing (Verification)

The new transducers have no different technological characteristics from those with the predicate device. The new transducers were tested with ultrasound console for electrical safety, EMC, performance, verification and validation. The biocompatibility was evaluated and meets the ISO10993 series standard and FDA guidance.

Summary of Clinical Tests:

The subject of this premarket submission, did not require clinical studies to support substantial equivalence.

Conclusion:

KOLO Considers the Evolution XHD Series Ultrasound Diagnostic System to be as safe, as effective, and performance is substantially equivalent to the predicate device.