MAUI Imaging
% Prabhu Raghavan
Principal Consultant
MDQR, LLC.
1790 Montemar Way
SAN JOSE CA 95125

October 25, 2023

Re: K230511
Trade/Device Name: K3900 Ultrasound Imaging System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic Pulsed Echo Imaging System
Regulatory Class: Class II
Product Code: IYO, ITX
Dated: September 27, 2023
Received: September 28, 2023

Dear Prabhu Raghavan:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Yanna S. Kang -S

Yanna Kang
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)*
K230511

Device Name
K3900 Ultrasound Imaging System

Indications for Use *(Describe)*
The K3900 Ultrasound Imaging System is intended for use by a qualified healthcare personnel in environments where healthcare is provided for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); and Intraoperative (abdominal, thoracic and vascular).

Modes of operation: B-Mode.

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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MAUI IMAGING

510(k) Summary for K230511

Prepared in accordance with the requirements of 21 CFR 807.92

Submitter Information [807.92(a)(1)]

Submitter/Applicant	David Specht, Chairman and CEO, MAUI Imaging 3600 136th PL SE, Ste 300, Bellevue, WA 98006 Email: david.specht@mauiimaging.com Phone: (408) 744-1127
Primary Regulatory Correspondent	Prabhu Raghavan Regulatory Consultant for MAUI Imaging Principal Consultant, MDQR Solutions, LLC. Phone: 408-316-5707 Email: prabhu@mdqr.solutions
Secondary Regulatory Correspondent	Roberta (Bobbi) Druyor-Sanchez Regulatory Consultant for MAUI Imaging Partner, NDA Partners, LLC. Phone: 480-216-5377 Email: sanchezbobbi@ndapartners.com
Date Prepared	October 25, 2023

Device Information [807.92(a)(2)]

Trade Name	K3900 Ultrasound Imaging System
Product Codes	IYO, ITX
Generic/Common Name	Ultrasonic Pulsed Echo Imaging System
Regulation	§ 892.1560
Device Class	II

Predicate Information [807.92(a)(3)]

Predicate(s)	K152309, GE LOGIQ E9, GE® Medical Systems Ultrasound and Primary Care Diagnostics

Device Description [807.92(a)(4)]

The K3900 Ultrasound Imaging System ("K3900") is a Track 3 general purpose ultrasound imaging system. The device generates and collects ultrasonic pulsed echo data via a transducer that is then digitized for further processing. The processing includes beamforming, image processing, and image optimization that then outputs an ultrasound image. This image may be displayed on a tablet or common displays through HDMI for general purpose radiological evaluation. The K3900 consists of an ultrasound transducer, a processing unit that manages the transducer and all data processing, and a tablet that provides the user interface to operate the device, view and analyze the ultrasound dataset, and manage patient study sessions.

The K3900 utilizes "ping" technology. In contrast to phased array transmission that transmit along predetermined scan lines using a large number of transducer elements with multiple focal regions, a ping is an unfocussed pulse transmitted by a limited set of transducer elements. Since the transmitted pulses are unfocussed, no beamforming or focusing is performed on the transmit side. Beamforming to create the ultrasound image is entirely done on the receive side, i.e., the process of combining the echo information is done by utilizing all of the receiver element data. In the predicate device, the beamforming process is split between the transmit side and the receive side, i.e., part of the beamforming is done by transmitting a focused pulse of ultrasound waves, and additional signal processing is conducted on the received echo data. This is a minor difference in signal processing and both the subject and predicate devices achieve the same imaging results. The differences in beamforming methods, which have been verified and validated through performance testing do not raise different questions of safety or effectiveness and demonstrate substantial equivalence to the predicate device.

Indications for use [807.92(a)(5)]
The K3900 Ultrasound Imaging System is intended for use by a qualified healthcare personnel in environments where healthcare is provided for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); and Intraoperative (abdominal, thoracic and vascular).

Modes of operation: B-mode.

Substantial Equivalence
The K3900 Ultrasound Imaging System subject device has the same intended use, and substantially equivalent physical characteristics, technological characteristics and software as the K152309, GE LOGIQ E9 predicate device. A comparison of the two devices is provided in the table below.

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]

Feature	**K3900 Ultrasound Imaging System (Subject Device)**	**LOGIQ E9 (K152309) (Predicate Device)**
Intended Use	Ultrasound imaging and evaluation of adults and pediatric patients	Ultrasound imaging and evaluation of adults and pediatric patients
Product Code	IYO, Ultrasonic Pulsed Echo Imaging System ITX, Diagnostic Ultrasonic Transducer	IYO, Ultrasonic Pulsed Echo Imaging System ITX, Diagnostic Ultrasonic Transducer IYN, Ultrasonic Pulsed Doppler Imaging System
Regulation	892.1560, Ultrasonic pulsed echo imaging system	892.1550, Ultrasonic pulsed doppler imaging system 892.1560, Ultrasonic pulsed echo imaging system
Classification	Class II	Class II

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]

Feature	**K3900 Ultrasound Imaging System (Subject Device)**	**LOGIQ E9 (K152309) (Predicate Device)**
Indications for Use	The K3900 Ultrasound Imaging System is intended for use by a qualified healthcare personnel in environments where healthcare is provided for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); and Intraoperative (abdominal, thoracic and vascular). Modes of operation: B-mode.	The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (abdominal, thoracic and vascular).
Contact Type	Body surface, intraoperative	Body surface, Cavitary (TV, TR, TE) and intraoperative
Transducer model, type	MAUI3-Concave-192, Curved Array Transducer	GE C1-6D, Curved Array Transducer
Number of Elements	Approximately 192	Approximately 192
Imaging Modes	B-mode	B, M, Color M, Color & Power Doppler, Pulsed & CW Doppler and various combinations: B/M B/PW, Color/Pwr/PW. Harmonic, Coded Pulse, Realtime 3D & Multi-plane, Elastography Imaging, Shear wave elastography (SWE)
Beamforming	Beamforming is performed on the receive side only.	Beamforming on both the transmit side, i.e., when sending the ultrasound pulses and on the receive side, i.e., when processing the ultrasound echoes.
Controls and Display	Tablet-based touch screen controls with display. HDMI output to secondary external display	Adjustable height control panel with touch screen and tilt/swivel LCD type image monitor

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]

Feature	K3900 Ultrasound Imaging System (Subject Device)	LOGIQ E9 (K152309) (Predicate Device)
Safety Compliance	• IEC60601-1, Medical Electrical equipment; General requirements for safety. • IEC60601-1-2, Medical Electrical equipment; Electromagnetic Compatibility. • ISO10993-1, Biological evaluation of medical devices. • FDA Track 3 • IEC 60601-2-37, Medical Electrical equipment; Particular requirements for safety of ultrasonic medical diagnostic and monitoring equipment. • IEC 62359, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields	• IEC60601-1, Medical Electrical equipment; General requirements for safety. • IEC60601-1-2, Medical Electrical equipment; Electromagnetic Compatibility. • ISO10993-1, Biological evaluation of medical devices. • FDA Track 3 • IEC 60601-2-37, Medical Electrical equipment; Particular requirements for safety of ultrasonic medical diagnostic and monitoring equipment. • FDA Track 3, Compliance with Output Display Standard NEMA UD 3-2004 when connected to a GE Ultrasound system

Performance Data [807.92(b)]
All necessary testing was conducted on K3900 Ultrasound Imaging System to support a determination of substantial equivalence to the predicate device.

Nonclinical Testing Summary [807.92(b)(1)]
MAUI Imaging has conducted bench performance testing of the K3900 subject device to verify and validate that the device requirements and specifications and to demonstrate that any differences between the subject and predicate device do not raise different questions of safety or effectiveness. Additional testing to support the substantial equivalence between the subject and predicate device includes:

- Evaluation of biocompatibility per ISO 10993-1,
- Electrical safety testing per IEC 60601-1,
- Electromagnetic compatibility per IEC 60601-1-2,
- Performance of the ultrasound safety, controls, and display in accordance with IEC60601-2-37:2015 and IEC 62359: 2017 to demonstrate that the device is within safety limits as well as requirements for a Track 3 ultrasound imaging device per FDA Guidance, "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers", dated February 2023, and
- Human factors usability testing

Clinical Testing Summary [807.92(b)(2)]
Clinical performance testing was conducted to validate that a healthcare professional would get equivalent imaging from the K3900 subject device as compared to the GE LOGIQ E9 predicate device. MAUI collected comparative ultrasound imaging data under an IRB approved study protocol at a radiology clinic where volunteers were recruited. After obtaining informed consent, a radiologist captured ultrasound images from both devices. Side-by-side comparisons of the still images of numerous anatomical structures showed that the imaging from the subject device was substantially equivalent to the predicate.

Conclusions [807.92(b)(3)]
The K3900 has the same intended use, indications for use and similar technological characteristics as the predicate. The minor differences in technological characteristics have been analyzed and addressed through software verification and validation testing. The testing results demonstrate that differences between the subject and predicate device do not raise different questions of safety or effectiveness. Therefore, the K3900 is substantially equivalent to the predicate device