July 18, 2022

GE Medical Systems Ultrasound & Primary Care Diagnostics LLC
% Lee Bush
Regulatory Affairs Director
9900 W. Innovation Drive
WAUWATOSA WI 53226

Re: K221148
Trade/Device Name: Vivid iq
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: July 1, 2022
Received: July 5, 2022

Dear Lee Bush:

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

Michael D. O'Hara, Ph.D.
Deputy Director
DHT 8C: Division of Radiological Imaging
and Radiation Therapy Devices
OHT 8: 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)*

K221148

Device Name

Vivid iq

Indications for Use *(Describe)*

The Vivid iq is high-performance compact diagnostic ultrasound system designed for cardiovascular and shared services. It is intended for use by Healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid.Vivid iq clinical applications include: Fetal/Obstetrics, Abdominal (includes GYN), Pediatric, Small Organ (includes breast, testes, thyroid), Neonatal Cephalic, Adult Cephalic, Cardiac (includes Adult and Pediatric), Peripheral Vascular, Musculoskeletal Conventional, Musculoskeletal Superficial, Urology (Including prostate), Transcranial, Transrectal, Transvaginal, Transesophageal, Interventional Guidance (including Biopsy), Thoracic/Pleural, Intraoperative(Vascular), Intracardiac and Intraluminal. Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M, Power Doppler, Harmonic Imaging, Real-Time (RT) 3D Mode (4D), Coded Pulse and Combined modes: B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Color/CWD, B/Power/PWD. The device is intended for use in an indoor hospital environment including echo lab, other hospital settings, operating room, Cath lab and EP lab, in private medical offices, and in limited settings outside of professional Healthcare facilities.

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 K221148

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

Date:	July 12, 2022
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Lee Bush Regulatory Affairs Director GE Healthcare T: (262)309-9429
Secondary Contact Person:	Yuan Wang Regulatory Affairs Leader GE Healthcare
Device Trade Name:	Vivid *iq*
Common/Usual Name:	Diagnostic Ultrasound System
Classification Names:	Class II
Product Code(s):	Ultrasonic Pulsed Doppler Imaging System. 21CFR 892.1550, 90- IYN; Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO; Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Predicate Device:	Vivid *iq* (K200708), Diagnostic Ultrasound System
Classification Names:	Class II
Product Code(s):	Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550, 90-IYN; Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO; Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Reference Device:	Vivid E95 (K173341), Diagnostic Ultrasound System
Classification Names:	Class II
Product Code(s):	Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550, 90-IYN; Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO; Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
Reference Device:	Venue Go (K202233), Diagnostic Ultrasound System
Classification Names:	Class II
Product Code(s):	Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550, 90-IYN; Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO; Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX
	Versana Premier (K210438), Diagnostic Ultrasound System

Reference Device:	Class II
Classification Names:	Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550, 90-IYN;
Product Code(s):	Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO; Diagnostic Ultrasound Transducer, 21 CFR 892.1570, 90-ITX

Device Description:
The proposed Vivid *iq* system is a general-purpose, Track 3, diagnostic ultrasound device, primarily intended for cardiovascular diagnostic use and shared service imaging. It is an ultrasound imaging & analysis system, consisting of a compact console with control panel including a track pad, color LCD Touch Panel that includes an on-screen alfa-numeric keyboard. The system also has an optional height-adjustable cart for comfortable standing and sitting positions. An extended battery is integrated within the Vivid *iq* cart and provides additional power for longer scanning time.

There are options for image storage, USB wireless connectivity, cardiac signal input for cardiac gating and output capabilities to printing devices. Vivid *iq* utilizes a variety of electronic array transducers operating in linear, curved, sector/phased array, matrix array, or dual array format, including dedicated CW transducers and real time 3D transducer. The system can also be used with compatible ICE transducers.

The system includes electronics for transmit and receive of ultrasound data, ultrasound signal processing, software computing, hardware for image storage, hard copy printing, and network access to the facility through both LAN and wireless (supported by use of a wireless LAN USB-adapter) connection.

Intended Use/Indication For Use:
The Vivid *iq* is high-performance compact diagnostic ultrasound system designed for Cardiovascular and Shared Services. It is intended for use by qualified and trained Healthcare professionals for Ultrasound imaging, measurement, display and analysis of the human body and fluid.

Vivid *iq* clinical applications include: Fetal/Obstetrics, Abdominal (includes GYN), Pediatric, Small Organ (includes breast, testes, thyroid), Neonatal Cephalic, Adult Cephalic, Cardiac (includes Adult and Pediatric), Peripheral Vascular, Musculoskeletal Conventional, Musculoskeletal Superficial, Urology (Including prostate), Transcranial, Transrectal, Transvaginal, Transesophageal, Interventional Guidance (including Biopsy), Thoracic/Pleural, Intraoperative(Vascular), Intracardiac and Intraluminal. Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M, Power Doppler, Harmonic Imaging, Real-Time (RT) 3D Mode (4D), Coded Pulse and Combined modes: B/M, B/Color M, B/PWD, B/CWD, B/Color/PWD, B/Color/CWD, B/Power/PWD. The device is intended for use in an indoor hospital environment including echo lab, other hospital settings, operating room, Cath lab and EP lab, in private medical offices, and in limited settings outside of professional Healthcare facilities.

Technology:
The Vivid *iq* employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

The proposed Vivid *iq* system is substantially equivalent to the predicate device Vivid *iq* and reference devices with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

The following is an overview of the differences between the proposed Vivid *iq* and its predicate device.

Indications for use:

The proposed Vivid *iq* and predicate Vivid *iq* (K200708) have similar clinical indications for use, except for:

- Added Thoracic/Pleural application, which was cleared on reference device Venue Go (K202233).
- Urology (Including prostate) is listed independently instead of within Abdominal as it was in the predicate Vivid *iq* (K200708). There is no change in imaging or the product. No impact to safe or effective use.

Transducer and modes:

- The proposed Vivid *iq* and predicate Vivid *iq* (K200708) have identical imaging modes.
- The proposed Vivid *iq* and predicate Vivid *iq* (K200708) transducers are similar, except for:
  - Addition of 10T-D, which was first cleared on Vivid E95 (K173341). The clinical applications and imaging modes of 10T-D are similar on the proposed Vivid *iq* as they are on the reference device Vivid E95 (K173341).
  - Addition of L4-20t-RS, which was first cleared on Venue Go (K202233). The clinical applications and imaging modes of L4-20t-RS are similar on the proposed Vivid *iq* as they are on the reference device Venue Go (K202233).
- The Thoracic/Pleural application is added to the transducers:
  - 3Sc-RS,6S-RS, 9L-RS, 12L-RS, ML6-15-RS, L8-18i-RS, C1-5-RS, 8C-RS, and L4-20t-RS based on the clearance of reference device Venue Go (K202233).
  - 4C-RS based on the clearance of reference device Versana Premier (K210438).
  - 12S-RS is a similar transducer to 6S-RS cleared with reference device Venue Go (K202233)
  - M5Sc-RS is a similar transducer to 3Sc-RS cleared with reference device Venue Go (K202233)

Software:

- Added workflow enhancements tools: Dual Crop, Pre-Post Compare, Image Spooler
- Updates made to: 2D Color Flow, Flexi-Slice, Launchpad
- Added Easy Auto EF -based on Auto EF 3.0 (includes AI Auto ROI algorithm)
- Added Easy AFI LV -based on AFI 3.0 (includes AI Auto ROI algorithm)
- Added Spline Tool - area, circumference, and volume measurement method
- Added Strain Elastography feature added, cleared in Versana Premier (K210438)
- Added Imaging Insights Data Collection Support – provides device usage information
- Added Probe check (Transducer Element Check)

Accessories:

- Added compatible OEM biopsy guide accessory compatibility for the L4-20t-RS transducer

Summary of Non-Clinical Tests:

Vivid *iq* is 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 standards. The Vivid *iq* complies with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety and Essential Performance, 2005/ A2:2012
- 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
- IEC 60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, Ed. 2.1, 2015
- ISO 10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing Within A Risk Management Process, 2009
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017
- ISO 14971, Application of risk management to medical devices, 2019
- NEMA PS 3.1 – 3.20, Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology), 2016

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

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Performance testing (Verification)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

<u>AI Summary of Testing: Easy Auto EF and Easy AFI LV</u>

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance

- The accuracy of the AI algorithm (average dice score) as tested on datasets from different countries, is 92% or higher; as tested on datasets from different scanning views, is 91% or higher; as tested on dataset from different left ventricle volumes, is 92% or higher.
- The number of individual patients' images were collected from:
  45 exams from assumed 45 patients (exact number of patients unknown due to anonymization of dataset).
- The number of samples, if different from above, and the relationship between the two:
  135 images extracted from the 45 exams

Demographic distribution including:

- Gender: Unknown, due to data anonymization during data collection

- Age: Adult, specific age unknown
- Ethnicity/Country: Europe, Asia, US

Information about clinical subgroups and confounders present in the dataset:

- During testing of the AI algorithm, we have included images from different countries, from different scanning views, and a range of different LV Volumes

Information about equipment and protocols used to collect images:

- Mix of data from across 5 different probes and 4 different Console variants. The data collection protocol was standardized across all data collection sites.

Information about how the reference standard was derived from the dataset (i.e., the "truthing" process)

- For all datasets, two certified cardiologists performed manual delineation, then reviewed the annotations for each other. A consensus reading was first done whereby the two cardiologists discussed if they agreed on or not. A panel of experienced experts further reviewed annotations that the two cardiologists could not agree on.
- Hence, the ground truth used are the annotations that the two cardiologists agreed with each other, and the consensus annotations achieved in the review meeting by a panel of experienced experts.

Description of how independence of test data from training data was ensured.

- To ensure that the testing dataset is not mixed with the training data, we used datasets from different clinical sites for testing as compared to the clinical sites for training.

Summary of Clinical Tests:

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

Conclusion:

GE Healthcare considers the Vivid *iq* to be as safe, as effective, and performance is substantially equivalent to the predicate and reference devices.