GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
% Tracey Ortiz
Regulatory Affairs Director
9900 W. Innovation Drive
WAUWATOSA WI 53226

September 9, 2020

Re: K200708
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 20, 2020
Received: July 21, 2020

Dear Tracey Ortiz:

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: 06/30/2020
See PRA Statement below.

510(k) Number
K200708

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 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, Urology), Pediatric, Small Organ (includes breast, testes, thyroid), Neonatal Cephalic, Adult Cephalic, Cardiac (includes Adult and Pediatric), Peripheral Vascular, Musculoskeletal Conventional, Musculoskeletal Superficial, Transcranial, Transrectal, Transvaginal, Transesophageal, Interventional Guidance (including Biopsy), 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.

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510(k) Summary

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

Date: July 20, 2020

Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics
9900 Innovation Drive
Wauwatosa, WI 53226

Primary Contact Person: Tracey Ortiz
Regulatory Affairs Director
GE Healthcare
T:(262)676-6120

Secondary Contact Person: Wang Yuan
Regulatory Affairs
GE Healthcare

Device Trade Name: Vivid *iq*

Common/Usual Name: Diagnostic Ultrasound System

Classification Names: Class II
IYN (primary), IYO, ITX (secondary)

Product Code:
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* (K181727)

Reference Devices: Vivid T8 (K160078)
Vivid E95 (K181685)
Versana Balance (K191792)
Vivid S70N (K200497)

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. 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 linear, sector, convex, and phased array transducers which provide high imaging capability, supporting all standard acquisition modes.

Intended 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, Urology), Pediatric, Small Organ (includes breast, testes, thyroid), Neonatal Cephalic, Adult Cephalic, Cardiac (includes Adult and Pediatric), Peripheral Vascular, Musculoskeletal Conventional, Musculoskeletal Superficial, Transcranial, Transrectal, Transvaginal, Transesophageal, Interventional Guidance (including Biopsy), 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 and reference devices.

Determination of Substantial Equivalence:

Comparison to Predicate Device

- The Vivid *iq* system is substantially equivalent to the predicate device with regards to intended use, imaging capabilities, technological characteristics and safety and effectiveness. There are no additional clinical applications, however the indications for use wording has been modified to align with the new ultrasound guidance, identify users similar to reference device Versana Balance (K191792), and provide information on the environments the system can be used in.
- The Vivid *iq* and predicate Vivid *iq* (K181727) have the same transducers
- Adding combine modes B/Color M, B/CWD and B/Color/CWD to 6VT-D transducer already cleared on Vivid E95(K181685).
- AI Auto Measure – 2D: same feature as cleared on Vivid S70N(K200497). It is AI (Artificial Intelligence) based Cardiac Auto 2D feature that enables automated measurements on a PLAX image.
- AI Auto Measure – Spectrum Recognition: same feature as cleared on Vivid S70N(K200497). It is AI based Spectrum Recognition feature that enables automated recognition of common Doppler spectra and automatically starts the Auto Doppler measurement or opens the appropriate manual measurement folder.
- AFI 3.0: same feature as cleared on Vivid S70N(K200497), has the ability to analyze the left ventricle on both GEHC raw data images and DICOM images from 3rd party ultrasound scanners
- Auto EF 3.0: same feature as cleared on Vivid S70N(K200497), has the ability to assess LV function on raw data images acquired with GEHC scanners as well as on DICOM images from other vendors systems.
- AFI RV: same feature as cleared on Vivid S70N(K200497). It is a parametric tool giving quantitative data for right ventricular longitudinal global strain, free wall strain and segmental strain derived from the apical 4-chamber RV focused view.
- AFI LA: same feature as cleared on Vivid S70N(K200497). It provides quantitative data for left atrial (LA) global strain. The tool also supports

measurements of LA volumes and emptying fraction (EF).

- HD Color: same feature as cleared on Vivid S70N(K200497). It enhances the perception of 4D color on a 2D monitor by addition of shadowing and specular reflection techniques, providing transparency control.
- 4D Markers: same feature as cleared on predicate Vivid *iq* (K181727). It is enhanced to allow the user to modify individual markers.
- Scan Coach: same feature as cleared on Vivid T8 (K160078), is designed to display information which helps user acquire the right scan plane.
- Stream Server: same feature as cleared on Vivid E95 (K181685), is modified slightly and enables the user to get guidance and/or second opinion by a remote viewer.
- Launchpad: same feature as cleared on Vivid S70N(K200497), allows the display and launch/starting of third-party software apps that have been installed on the system. Only apps that have been qualified and compatibility verified can be installed on the system.
- Adding additional lung imaging presets
- DICOM PDF Read: same feature as cleared on Vivid S70N (200497). The system supports read-only access to DICOM PDF reports created on a DICOM server.

Summary of Non-Clinical Tests:

The proposed Vivid *iq* has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to comply with applicable medical device safety standards. The Vivid *iq* complies with voluntary standards:

- AAMI/ANSI ES 60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance - 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements

and tests - Edition 4.0, 2014

- 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 - Edition 2.1, 2015
- ISO 10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition, 2009
- IEC 62359, Ultrasonic - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields - Edition 2.1, 2017
- ISO 14971, Application of risk management to medical devices, 2007
- NEMA PS 3.1 - 3.20, Digital Imaging and Communications in Medicine (DICOM) Set, 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 & Validation)
- Safety testing (Verification)

Transducer material and other patient contact materials are biocompatible.

Conclusion:

Summary of Clinical Tests:

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

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