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: K200851
Trade/Device Name: Vivid T8, Vivid T9
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: August 7, 2020
Received: August 10, 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
K200851

Device Name

Vivid T8, Vivid T9

Indications for Use *(Describe)*

The Vivid T9/Vivid T8 is a general-purpose ultrasound system, specialized for use in cardiac imaging. It is intended for use by qualified and trained Healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid. The device is intended for use in a hospital environment including echo lab, other hospital settings, operating room, Cath lab, and in private medical offices. The systems support the following clinical applications: 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, Transesophageal, Transrectal, Transvaginal, Interventional guidance (including Biopsy, Fluid Drainage), Intraoperative(Vascular). Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M, Power Doppler, Harmonic Imaging, Coded Pulse and Combined modes: B/M, B/PWD, B/Color/PWD, B/Power/PWD.

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

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

Date:	March 27, 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:	Xie Jian Regulatory Affairs
Device Trade Name:	Vivid T8/Vivid T9
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
Primary Predicate Device:	Vivid T8, Vivid T9 (K181934)
Reference Device(s):	Vivid iq (K181727) Vivid T8 (K160078) Vivid E95 (K181685) Versana Balance (K191792) Vivid S70N (K200497)
Device Description:	Vivid T8/Vivid T9 is a Track 3, diagnostic ultrasound system, which is primarily intended for cardiac imaging and analysis but also includes vascular and general radiology applications. It is a full featured diagnostic ultrasound system that provides digital acquisition, processing, analysis and display capability. The Vivid T8/Vivid T9 consists of a mobile console with control panel color LCD touch panel, LCD display monitor and optional image storage and printing devices. It includes a variety of

electronic array transducers operating in linear, curved, sector/phased array, matrix array, and dual array including dedicated CW 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 / Indications for Use:

The Vivid T9/Vivid T8 is a general-purpose ultrasound system, specialized for use in cardiac imaging. It is intended for use by qualified and trained Healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid. The device is intended for use in a hospital environment including echo lab, other hospital settings, operating room, Cath lab, and in private medical offices. The systems support the following clinical applications: 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, Transesophageal, Transrectal, Transvaginal, Interventional guidance (including Biopsy, Fluid Drainage), Intraoperative(Vascular). Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M, Power Doppler, Harmonic Imaging, Coded Pulse and Combined modes: B/M, B/PWD, B/Color/PWD, B/Power/PWD.

Technology:

The Vivid T8/Vivid T9 employs the same fundamental scientific technology as its predicate and reference devices.

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The Vivid T8/Vivid T9 is substantially equivalent to the predicate devices with regard to intended use, imaging capabilities, technological characteristics and safety and effectiveness.

The following is an overview of the differences between the proposed Vivid T8/Vivid T9 and its predicate.
Transducers and Modes:

- Adding ML6-15-RS probe which was previously cleared in Vivid iq (K181727).

Indications for Use:

- There are no additional clinical applications, however the statement wording has been modified to align with the new ultrasound guidance.

Features/Functionality additions:

- AI Auto Measure – 2D: same feature as cleared on Vivid S70N(K200497). It is AI (Artificial Intelligence) based Cardiac Auto 2D feature that enables semi-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), based on AFI 2.0, adds 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), based on Auto EF 2.0, adds 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), based on AFI 2.0, but modified for the right ventricle (RV). 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), based on AFI 2.0, but modified for the left atrium. It provides quantitative data for left atrial (LA) global strain. The tool also supports measurements of LA volumes and emptying fraction (EF).
- Scan Coach: cleared on Vivid T8 (K160078), is designed to display information which helps user acquire the right scan plane.

- Stream Server: Feature cleared in Vivid E95 (K181685), is modified slightly and enables the user to get guidance and/or second opinion by a remote viewer.

Hardware modification

- New CPU
- Introduce new LCD monitor
- Adding HDMI port
- Upgrade the USB2.0 to USB3.1

Summary of Non-Clinical Tests:

Vivid T8 / Vivid T9 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 standards. The Vivid T8 / Vivid T9 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, 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, 2007
- 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 & Validation)
- Safety testing (Verification)

Transducer material and other patient contact materials are biocompatible.

The subject of this premarket submission, Vivid T8 /Vivid T9, did not require clinical studies to support substantial equivalence.

Summary of Clinical Tests:

Conclusion: GE Healthcare considers the Vivid T8 / Vivid T9 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).