



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

July 23, 2020

Re: K200743

Trade/Device Name: Vivid E80/ Vivid E90/ Vivid E95  
Regulation Number: 21 CFR 892.1550  
Regulation Name: Ultrasonic pulsed doppler imaging system  
Regulatory Class: Class II  
Product Code: IYN, IYO, ITX  
Dated: June 19, 2020  
Received: June 22, 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](mailto: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

## Indications for Use

510(k) Number (if known)

K200743

Device Name

Vivid E80 / Vivid E90 / Vivid E95

Indications for Use (Describe)

Vivid E80 / Vivid E90 / Vivid E95 is a general-purpose ultrasound system, specialized for use in cardiac imaging. 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 including echo lab, other hospital settings, operating room, Cath lab and EP lab or in private medical offices. The systems support the following clinical applications: Fetal/Obstetrics, Abdominal (including renal, GYN), Pediatric, Small Organ (breast, testes, thyroid), Neonatal Cephalic, Adult Cephalic, Cardiac (adult and pediatric), Peripheral Vascular, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Urology (including prostate), Transesophageal, Transvaginal, Transrectal, Interventional Guidance (including Biopsy, Vascular Access), and Intraoperative (vascular). Modes of operation include: 3D, Real time (RT) 3D Mode (4D), B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse and Combined modes: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, 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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@fda.hhs.gov

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*



GE Healthcare  
510(k) Premarket Notification Submission

**510(k) Summary**

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

Date: March 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: Jan Tore Thollefsen  
Sr. Regulatory Affairs Manager

Device Trade Name: Vivid E80 / Vivid E90 / Vivid E95

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 E80 / Vivid E90 / Vivid E95 (K181685)

Reference Device(s): LOGIQ E9 (K163077)  
Vivid E80 / Vivid E90 / Vivid E95 (K170823)  
Vivid E80 / Vivid E90 / Vivid E95 (K150087)  
Vivid 7 (K051449)

Device Description: Vivid E80 / Vivid E90 / Vivid E95 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 E80 / Vivid E90 / Vivid E95 consists of a mobile console with a height-adjustable control panel, color LCD touch panel, OLED or LCD display monitor (alternatives) and optional image storage and printing devices. It includes a variety of



## GE Healthcare

### 510(k) Premarket Notification Submission

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 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 adapter) connection.

**Intended Use:** Vivid E80 / Vivid E90 / Vivid E95 is a general-purpose ultrasound system, specialized for use in cardiac imaging. 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 including echo lab, other hospital settings, operating room, Cath lab and EP lab or in private medical offices. The systems support the following clinical applications: Fetal/Obstetrics, Abdominal (including renal, GYN), Pediatric, Small Organ (breast, testes, thyroid), Neonatal Cephalic, Adult Cephalic, Cardiac (adult and pediatric), Peripheral Vascular, Musculo-skeletal Conventional, Musculo-skeletal Superficial, Urology (including prostate), Transesophageal, Transvaginal, Transrectal, Interventional Guidance (including Biopsy, Vascular Access), and Intraoperative (vascular). Modes of operation include: 3D, Real time (RT) 3D Mode (4D), B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse and Combined modes: B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD.

**Technology:** The Vivid E80 / Vivid E90 / Vivid E95 employs the same fundamental scientific technology as its predicate devices.

**Determination of Substantial Equivalence:** **Comparison to Predicate Devices**  
The Vivid E80 / Vivid E90 / Vivid E95 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 E80 / Vivid E90 / Vivid E95 and its predicates.  
Transducers and Modes:



## GE Healthcare

### 510(k) Premarket Notification Submission

- Adding the transducer ML6-15-D which was previously cleared in LOGIQ E9 (K163077).
- Adding the new transducer, 6Vc-D, having the same indications as 6S-D previously cleared for Vivid E80 / Vivid E90 / Vivid E95 (K181685). 6Vc-D can be used for 3D and real-time 3D (4D) imaging, similar to 4Vc-D already cleared for Vivid E80 / Vivid E90 / Vivid E95 (K181685).

#### 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: AI (Artificial Intelligence) based Cardiac Auto 2D feature that enables automated measurements on a PLAX images using similar process as IMT feature first released on Vivid 7, K051449 and manual workflow on predicate Vivid E95, K150087. This saves time compared to manual measurements, due to elimination of user interactions (clicks) by 79% (4 vs. 19). AI Auto Measure – 2D may also reduce inter-observer variability.
- AI Auto Measure – Spectrum Recognition: 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: based on AFI 2.0 (cleared in Vivid E80/E90/E95, K181685), adds the ability to analyze the left ventricle on both GEHC raw data images and DICOM images from 3<sup>rd</sup> party ultrasound scanners.
- Auto EF 3.0: based on Auto EF 2.0 (cleared in K181685), 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: based on AFI 2.0 (cleared in K181685) 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.



## GE Healthcare

### 510(k) Premarket Notification Submission

- AFI LA: based on AFI 2.0 (cleared in K181685) 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).
- Launchpad: 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.
- HD Color: enhances the perception of 4D color on a 2D monitor by addition of shadowing and specular reflection techniques, providing transparency control.
- Flexi-Light: enhances the perception of depth of 3D objects when visualized on a 2D monitor by use of advanced shadowing, reflection and shading in combination with depth rendering and use of adjustable virtual light sources.
- 4D Auto TVQ: new feature for quantification of tricuspid annulus and valve in 4D echocardiographic data. The feature is substantially equivalent to the feature for quantification of the Mitral Valve, 4D Auto MVQ, which is already present on the predicate Vivid E80 / Vivid E90 / Vivid E95 (K170823).
- DICOM PDF Read: The system supports read-only access to DICOM PDF reports created on a DICOM server.
- 4D Markers: Feature cleared in Vivid E80/E90/E95 (K181685), is modified to allow the user to modify individual markers.
- Zscore: Three Z-score sets of values added based on published literature - are being added to those previously cleared in Vivid E80/E90/E95 (K181685).

#### Summary of Non-Clinical Tests:

Vivid E80 / Vivid E90 / Vivid E95 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 E80 / Vivid E90 / Vivid E95 complies with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety and Essential Performance, 2005/ A2:2012



## GE Healthcare

### 510(k) Premarket Notification Submission

- 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 and Validation)
- Safety testing (Verification)

Transducer material and other patient contact materials are biocompatible.

#### Summary of Clinical Tests:

The subject of this premarket submission, Vivid E80 / Vivid E90 / Vivid E95, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the Vivid E80 / Vivid E90 / Vivid E95 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).