February 11, 2025

GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
Lee Bush
Regulatory Affairs Director
3200 N Grandview Blvd
WAUKESHA WI 53188

Re: K243620
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: November 22, 2024
Received: November 22, 2024

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 (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Marjan Nabili -S for

Yanna Kang, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243620

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), 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, Vascular access), 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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K243620

510(k) Summary

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

Date: Nov 22, 2024

Submitter: GE Medical Systems Ultrasound and Primary care Diagnostics, LLC
3200 N Grandview Blvd
Waukesha, WI 53188, USA

Manufacturer: GE Medical Systems (China) Co., Ltd.
No.19, ChangJiang Road, WuXi National Hi-Tech Dev. Zone,
214028 Jiangsu China

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Device Trade Name: Vivid *iq*
Common/Usual Name: Diagnostic Ultrasound System
Classification Names: Class II
Product Code: IYN (primary), IYO, ITX (secondary)
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: K221148 Vivid *iq*
Reference Device(s): K232186 LOGIQ e
K220619 Vivid S70N/S60N
K211524 LOGIQ Fortis

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

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 alphanumeric keyboard. The system also has standard height-adjustable new ergonomic mobile cart for comfortable standing and sitting positions. The Charge Box in the Mobile Cart provides Vivid *iq* up to 4 hours scanning time without power supply.

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: 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, Vascular Access), 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(s).

Determination of Substantial Equivalence:

Comparison to Predicates

The proposed Vivid *iq* is substantially equivalent to the predicate devices. The following is an overview of the differences between the Vivid *iq* and the predicate Vivid *iq* (K221148).

Indications for Use:
The proposed Vivid *iq* and predicate Vivid *iq* (K21148) have similar clinical indications for use, however the proposed device Vivid *iq* is adding Vascular Access which has been cleared on reference device Vivid S70N/S60N (K220619).

Transducers:

The proposed Vivid *iq* and predicate Vivid *iq* (K221148) transducers are similar, except for:

- Addition of two OEM Ultrasound Catheters (AcuNav Crystal Ultrasound Catheter (K233270) from SIEMENS Medical Solutions USA, Inc and SOUNDSTAR™ CRYSTAL Ultrasound Catheter (K240050) from Biosense Webster Inc.) to the compatible accessory list. The clinical indications and modes on the proposed Vivid *iq* are the same as on the predicate device Vivid *iq* (K221148)

Software Features/Functionality:

- Sleep mode: similar to Standby mode on cleared LOGIQ e (K232186). It helps reduce battery consumption and allows for longer time between battery charges, enabling up to 22% reduced daily power consumption and 22% extended portable echo usage.
- Clarity +: similar to Advanced SRI-HD on cleared LOGIQ Fortis (K211524), it is a real-time image processing/filtering technique that suppresses noise and graininess (reduces speckles) while sharpening boundaries and small structures.
- DICOM Encapsulated PDF report: allows PDF reports generated on the system to be transferred through DICOM data flows and stored in DICOM storage, in accordance with the DICOM standard.
- Remote Viewing: same as on cleared Vivid S70N(K220619), enables streaming of the main monitor over the local network. This feature is not for diagnostic use.
- Addition of Carto 3 Communication Options (K231207)
  - Digital Video Streaming: same as cleared on Vivid

S70N(K220619), digital video streaming of 2D and CF modes to OEM (Original Equipment Manufacturer) Carto 3 EP Navigation System V8.0 in addition to previously available analog/VGA output.

- One-click QuickApps shortcuts: allows users to maintain high-quality tissue and blood flow visualization during transition between high flow / low flow and superficial / deep scanning with only one-click on the main screen.

Accessories:

- Additional ICE Cord-RS CRYSTAL, to connect with AcuNav Crystal Ultrasound Catheter (K233270) and SOUNDSTAR CRYSTAL Ultrasound Catheter (K240050)
- Additional wireless adapter Netgear A8000
- Additional Transend DVD writer

Summary of Non-Clinical Tests:

The device 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 conform with applicable medical device safety standards. The proposed Vivid *iq* complies with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/A2:2021
- AAMI TIR69:2017/(R2020) Technical Information Report Risk management of radio-frequency wireless coexistence for medical devices and systems
- 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, Edition 4.1, 2020
- IEC 60601-2-37, Medical Electrical Equipment – Part 2-37: Particular Requirements for the Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment, Edition 2.1, 2015
- ISO 10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing Within Risk Management Process, Fifth edition, 2018
- 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), 2022d
- IEC 62359, Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to

medical diagnostic ultrasonic fields, Edition 2.1, 2017

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 materials and other patient contact materials are biocompatible.

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

Conclusion:
Based on the equipment design similarities, conformance to recognized performance standards, and performance testing, GE HealthCare considers the proposed Vivid *iq* to be as safe, effective, and performs in a substantially equivalent manner as the predicate Vivid *iq* (K221148).