



February 16, 2023

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

Re: K223832

Trade/Device Name: Vivid S60N / Vivid S70N
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: December 21, 2022
Received: December 22, 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/pmnmn.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,


Yanna S. Kang -S

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

Indications for Use

510(k) Number (if known)
K223832

Device Name
Vivid S60N / Vivid S70N

Indications for Use (Describe)

Vivid S60N/Vivid S70N 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, Intra-cardiac and Intra-luminal, Interventional Guidance (including Biopsy, Vascular Access), Thoracic/Pleural, and Intraoperative (vascular). Modes of operation include 3D/4D Imaging mode, 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.

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GE Healthcare
510(k) Premarket Notification Submission

510(k) Summary

K223832

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

Date: December 21, 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: Nadine Gebhard- Höflinger
Regulatory Affairs Leader
GE Healthcare

Device Trade Name: Vivid S60N / Vivid S70N
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

Primary Predicate Device: Vivid S60N, Vivid S70N (K220619), 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: NUVISION™ NAV (K223766), Diagnostic Intravascular Catheter,
Ultrasound

Classification Names: Class II

Product Code(s): OBJ



GE Healthcare

510(k) Premarket Notification Submission

Reference device: CARTO 3 EP Navigation System with CARTOSOUND 4D Version V7.4 (K223733), Programable Diagnostic Computer

Classification Names: Class II

Product Code(s): DQK

Device Description:

Vivid S60N / Vivid S70N is a Track 3, diagnostic ultrasound system for use by qualified and trained healthcare professionals, 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 S60N / Vivid S70N consists of a mobile console with a height-adjustable 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 or dual array format, including dedicated CW transducers and real time 3D transducer. System can also be used with compatible ICE (Intra Cardiac Echocardiography) 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:

Vivid S60N/Vivid S70N 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, Intra-cardiac and Intra-luminal, Interventional Guidance (including Biopsy, Vascular Access), Thoracic/Pleural, and Intraoperative (vascular). Modes of operation include: 3D/4D Imaging mode, 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.



GE Healthcare
510(k) Premarket Notification Submission

Technology:

The Vivid S60N/Vivid S70N employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence:

The proposed Vivid S60N/Vivid S70N systems are substantially equivalent to the predicate Vivid S60N/ S70N and reference devices with regards to intended use, indications for use, imaging capabilities, technological characteristics, imaging modes, hardware, and safety and effectiveness.

The following is an overview of the differences between the proposed Vivid S60N / Vivid S70N and its predicate and reference devices.

Features/Functionality:

- Addition of Carto 3 Communication Options (K223733)
 - Digital Video Streaming for 2D, CF, MP, 4D modes (both 2D ICE and 4D ICE) with OEM (Original Equipment Manufacturer) Carto 3 EP Navigation System with CARTOSOUND 4D Version V7.4 in addition to previously available analog/VGA output.

Transducers and Modes:

- Addition of OEM ICE catheter (NUVISION™ NAV from Biosense Webster, Inc., K223766) to the compatible accessories list. The clinical indications and modes are the same on the proposed Vivid S60N/S70N device as they are on the predicate Vivid S60N/S70N device which already included 4D ICE catheter support.

Instruction for Use:

- Addition of addendum for added OEM ICE catheter



GE Healthcare
510(k) Premarket Notification Submission

Summary of Non-Clinical Tests:

Vivid S60N / Vivid S70N 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 S60N / Vivid S70N 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 material and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, Vivid S60N and Vivid S70N, did not require clinical studies to support substantial equivalence.

Conclusion:

GE Healthcare considers the Vivid S60N / Vivid S70N to be as safe, as effective, and performance is substantially equivalent to the primary predicate device.