July 10, 2025

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

Re: K251169
Trade/Device Name: Vivid Pioneer
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 15, 2025
Received: April 15, 2025

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.

510(k) Number *(if known)*
K251169

Device Name
Vivid Pioneer

Indications for Use *(Describe)*
Vivid Pioneer 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 or sonographer for ultrasound imaging, measurement, display and analysis of the human body and fluid.

Vivid Pioneer 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, lntra-luminal and lnterventional Guidance (including Biopsy, Vascular Access), Thoracic/Pleural and lntraoperative (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.

510(k) Summary

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

510(k) Number:	K251169
Date:	July 10, 2025
Submitter:	GE Medical Systems Ultrasound and Primary care Diagnostics, LLC 3200 N Grandview Blvd Waukesha, WI 53188, USA
Manufacturer:	GE Vingmed Ultrasound AS Strandpromenaden 45 3191 Horten, Norway
Primary Contact Person:	Lee Bush Regulatory Affairs Director GE HealthCare T:(262) 309-9429
Alternate Contact Person:	Jan Tore Thollefsen Senior Regulatory Affairs Manager GE HealthCare T: +47 9321 5640
Device Trade Name:	Vivid Pioneer
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:	K220882 Vivid E95
Reference Device(s):	K223832 Vivid S70N/S60N K231989 LOGIQ E10 K243620 Vivid iq K231965 Voluson Expert 22/20/18 K181685 Vivid E95 K170823 Vivid E95 K200743 Vivid E95
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 Pioneer is a general purpose, Track 3, diagnostic ultrasound system, which is primarily intended for cardiac imaging and analysis but also includes vascular and general radiology applications. It provides digital acquisition, processing, display and analysis capabilities. It consists of a mobile console with a height-adjustable control panel, color LCD touch panel, and a display monitor. Vivid Pioneer 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. The proposed Vivid Pioneer can be used with the stated compatible OEM ICE transducers. The system includes capability to output data to other devices like printing devices.

The user-interface includes an operator control panel, a 23.8" High-Definition Ultrasound LCD type of display monitor (mounted on an arm for rotation and / or adjustment of height), a layout of pre-defined user controls (hard-keys) and a 15.6-inch multi-touch LCD panel with mode- and operation dependent soft-keys.

The operator panel also includes two loudspeakers for audio, shelves for convenient placement of papers or accessories, and 6 holders with cable management for the connected transducers.

The lower console is mounted on 4 rotational wheels with brakes, for ergonomic transport and safe parking. The lower console also includes all 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: Vivid Pioneer 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 or sonographer 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, Intra-luminal and Interventional Guidance (including Biopsy, Vascular Access), Thoracic/Pleural 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 Pioneer employs the same fundamental scientific technology as its predicate device(s)

Determination of Substantial Equivalence:

Comparison to Predicates.

The proposed Vivid Pioneer is substantially equivalent to the predicate devices. The following is an overview of the differences between the Vivid Pioneer and the predicate Vivid E95 (K220882).

Indications for Use

The proposed Vivid Pioneer and predicate Vivid E95 (K220882) have identical clinical indications for use.

Transducers

The proposed Vivid Pioneer and predicate Vivid E95 (K220882) transducers are similar, except for:

- Addition of new 6Sc-D transducer with identical Indications for Use and identical Modes of Operation as the predicate 6S-D cleared with Vivid E95 (K220882)

Software Features/Functionality

- **4D Auto LHQ**, combining two predicate tools, 4D Auto LAQ and 4D Auto LVQ, both previously available in Vivid E95 (K220882).
- **4D Auto MVQ**, available in Predicate Vivid E95 (K220882), is updated with 4D ColorFlow capabilities.
- **4D Auto TVQ**, available in predicate Vivid E95 (K220882), is updated with 4D ColorFlow capabilities.
- **AI Cardiac Auto Doppler:** AI based algorithm for auto-tracing of additional doppler spectrums added to the predicate Cardiac Auto Doppler available in the predicate Vivid E95 (K220882), introducing additional heart valve related measurements compared to the predicate Spectrum Recognition algorithm available in Vivid E95 (K220882).
- **TSP Height:** Tool used to visualize and measure the distance between the mitral anulus and the tip of the catheter during guided transeptal puncture procedures. Substantially equivalent to caliper distance measurement available in predicate Vivid E95 (K220882)
- **LAA Device compression**: A manual measurement- and calculation tool that allows manual caliper measurements of the width and the length of the Left Atrial Appendage, calculating compression in percentage on a chosen LAA-closure device size. This helps with LAA device sizing. Measurements are based on the regular caliper tool available in Vivid Pioneer and the predicate Vivid E95 (K220882).
- **LAA Sizing Tool**: Used for tracing the Left Atrial Appendage lumen and for measuring basic parameters within the traced area. Based on ROI tracing and area measurement tool in predicate Vivid E95 (K220882).
- **Auto Tissue:** A Real-time image processing algorithm for automatic gain optimization of B-mode images to help the user minimize manual gain and TGC adjustment. Predicate feature named Auto Tissue Enhancement in Vivid E95 (K220882).
- **Clarity+ for 2D:** Multiple SRI filter settings, ranging from zero to strong filtering made available to the user in real time with a Clarity+ control. Available with reference Vivid iq (K243620).
- **Clarity+ for 4D:** A real-time processing/filtering technique that utilizes volumetric data vs traditional 2D-based filtering.

Available as V-SRI filter in reference Voluson Expert 22/20/18 (K231965)

- **cSound Pioneer:** Imaging reconstruction algorithm substantially equivalent to the cSound Adapt functionality in Vivid E95 (K220882). With Vivid Pioneer the predicate cSound Adapt image reconstruction algorithm is enhanced to also perform:
  - **Real-time correction on Color data** in addition to the real-time corrections made on tissue data caused by inhomogeneities in the speed of sound, and:
  - Real-time sharpening to improve the spatial resolution in axial and lateral directions, also known as **cSound Sharp.**
  - **Soft rendering**, a volume (4D) visualization mode offered as an alternative to the standard volume rendering of the predicate Vivid E95 (K220882).
  - **Realtime 3D Color Flow, 2D Color Flow**: Changes to color- flow related velocity-dependent filtering, to spatial filtering, and to the adaptive correction of variations in the speed of sound, improving functionality available in the predicate Vivid E95 (K220882).
- **RadiantFlow:** Applying shading to regular 2D color flow imaging. Same as Radiant Flow in reference Voluson Expert (K231965).
- **Silhouette:** Visualization of the boundaries between cavities and cardiac tissue structures and devices. A modification based on Flexi-Light imaging mode in Vivid E95 (K200882) and HD Live Silhouette in reference Voluson Expert 22/20/18 (K231965).
- **AI FlexiViews LAA**: AI based workflow tool to help localize the LAA (Left Atrial Appendage) anatomical structure in real-time 2D or Biplane images with a single button press. Similar functionality to 4D Zoom Prepare, 4D, and Flexi-Slice features in Vivid E95 (K220882).
- **CT Fusion/ CT Fusion Live:** Added 4D ColorFlow visualization to the predicate CT Fusion / CTFusion Live from Vivid E95 (K220882).
- **2 Click Crop:** Modifications to the predicate Dual Crop workflow tool in Vivid E95 (K220882) now allowing up to 3 parallel crop planes.
- **2-Click Align:** Functionality added to the predicate Flexi-Slice in Vivid E95 (K220882), for Improved 4D workflow.

- **PDF Export to PACS server:** (aka DICOM Encapsulated PDF) To allow storing PDF reports to a DICOM/PACS server.
- **Archive:** With the proposed Vivid Pioneer both the patient archive and the operating system are encrypted.
- **Instant Store:** Background processing for storing images without impacting ongoing real time scanning.
- **Secure Wipe:** Admin user is allowed to securely delete all data on the device, including all Person Identifiable Information / Personal Health Information.
- **NTP Clock Sync:** Admin user is allowed to configure the system to do automatic clock synchronization to a selected Network Time Protocol server.
- **eDelivery:** The proposed Vivid Pioneer will enable download and install of partial system updates (patches) of the Windows OS made available from the GE HealthCare server.
- **Internal Battery:** Vivid Pioneer has an internal battery to avoid having to do full shutdown during transport in the clinic. In addition, Vivid Pioneer will allow a maximum of 5 minutes of ultrasound scanning at full battery in case of abrupt mains failure.

Accessories:

- Support for wireless adapter, Netgear A8000
- Compatibility with **CARTO 3** Navigation and mapping device and **Nuvision NAV** Intra Cardiac Catheter, both from Biosense Webster Inc, part of Johnson&Johnson MedTech, was added to Vivid Pioneer.

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 Pioneer 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), 2024e
- 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.

AI Auto Doppler Summary of Testing:

Summary test statistics and other results including acceptance criteria and information supporting the appropriateness of the characterized performance are provided below. The AI Auto Doppler feature utilizes 2 AI algorithms, Tissue Doppler and Doppler Trace, which are referenced below.

Testing dataset:

- Testing dataset representative of standard clinical practices used

to collect typical cardiac images in clinical environments were assessed by experts for accuracy.

- Tissue Doppler testing dataset included 4106 recordings from 805 individuals.
- Doppler Trace testing dataset included 3390 recordings from 1369 individuals.

Distribution of testing dataset (Demographics and Ultrasound System):

- Gender: Male and Female
- Age: Adult and Pediatric
- Ethnicity/Country: USA (several locations), Australia, France, Spain, Norway, Italy, Germany, Thailand, Philippines
- Ultrasound Console(s): Vivid E80, Vivid E95, Vivid E9, Vivid IQ, Vivid S70, Vivid T9, Vivid Q, Vivid Pioneer
- Probe(s): 6Sc, 6Vc, 3Sc, 4Vc, 4V, M5S, 6S, M4S, M5Sc, M5S, 12S, 9VT, 6VT, 10T

Information about clinical subgroups and confounders present in the testing dataset:

- The algorithm performance was verified across a range of confounders: Ethnicity/Country (USA - several locations, Australia, France, Spain, Norway, Italy, Germany, Thailand, Philippines), wide range of Vivid consoles, wide range of probes.

Performance demonstrated on the verification (testing) dataset:

- The verification requirement included a step to check for a feasibility score of more than 95%, as well as an expected accuracy threshold calculated as the mean absolute difference in percentage for each measured parameter.
- The verification requirement included a step to check mean percent absolute error across all cardiac cycles against a threshold. All clinical parameters, as performed by AI Cardiac Auto Doppler without user edits passed this check These results indicate that observed accuracy of each of the individual clinical parameters met the acceptance criteria.
- The performance of AI Cardiac Doppler algorithm was evaluated across two BMI groups (<25 and ⩾25) using a subset of the Vivid Pioneer dataset containing BMI data (41 patients, 433 Doppler measurements). Manual Doppler measurements, reviewed by clinical experts, served as reference values for assessing the AI results.

Performance was evaluated separately for tissue and flow Doppler parameters using a predefined metric quantifying agreement between manual and AI-derived peak velocities. For tissue Doppler, the mean performance metric was -0.002 (SD = 0.077) for BMI < 25 and -0.006 (SD = 0.081) for BMI ⩾ 25. For flow Doppler, the means were 0.021 (SD = 0.073) and 0.003 (SD = 0.057), respectively.

The number of total samples, if different from above, and the relationship between the two:

- Tissue Doppler development dataset included 1482 recordings from 4 unique clinical sites (not used for testing dataset).
- Doppler Trace development dataset included 2070 recordings from 4 unique clinical sites (not used for testing dataset).

Information about equipment and protocols used to collect images:

- Development dataset included images obtained with the M5Sc, M5S, 4Vc, 4V, M4S, 6S, 12S, 6Vc, 6VT probes on a variety of Vivid cardiovascular ultrasound systems (Vivid E80, Vivid E95, Vivid E9, Vivid 7, Vivid S70N)

Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): Ground truth annotations of the development and verification datasets were obtained as follows:

- In all Training, Validation, and Testing datasets, annotators performed manual measurements after assessing Doppler signal quality and ECG signal quality of curated images.
- Two cardiologists performed the annotations following US ASE based annotation guidelines.
- A review panel of five clinical experts provided feedback on the annotations which were corrected (as needed) until a consensus agreement was achieved between the annotators and reviewers.

Description of how independence of test data from training data was ensured:

- The testing dataset is selected from independent clinical research institutions that have never been used for training and validation (tuning), ensuring the elimination of potential data leakage.

AI FlexiViews LAA Summary of Testing:

Summary test statistics and other results including acceptance criteria and information supporting the appropriateness of the characterized performance are provided below.

Verification (testing) dataset:

- Verification dataset representative of standard clinical practices used to collect typical adult cardiac images in clinical environments were assessed by experts for accuracy.
- Verification dataset included 342 recordings from 84 individuals.

Distribution of verification dataset (Demographics and Ultrasound System):

- Gender: Male and Female
- Age: Adult
- BMI: 18.5-25, 25-30, >30
- Ethnicity/Country: USA, Norway, Italy, France, Philippines
- Ultrasound Console(s): Vivid E95, Vivid S70N, Vivid IQ, Vivid Pioneer
- Probe(s): 6VT

Information about clinical subgroups and confounders present in the verification dataset:

- The algorithm performance was verified across a range of confounders: Ethnicity/Country (USA, Norway, Italy, France, Philippines), BMI (18.5-25, 25-30, >30), TEE Angle (0-45, 45-90, 90-135, >135).

Expected performance:

- Greater than 80% success rate of LAA region localization and landmark extraction

Performance demonstrated on verification dataset

- The model achieved a verification success rate of 85%, with a sensitivity of 84.91% and a specificity of 91.82%
- Subgroup analysis by TEE angle demonstrated consistent model performance, with a success rate of 80% or higher across the feature-supported angle range of 0 to 100 degrees.
- Analysis of the subset with available BMI data showed strong model performance, with over 85% accuracy for individuals

with a BMI above 25.

The number of total samples, if different from above, and the relationship between the two:

- Total development dataset included 612 recordings from 5 unique clinical sites (not used for verification dataset).

Information about equipment and protocols used to collect images:

- Development dataset included images obtained with the 6VT probe on a variety of Vivid cardiovascular ultrasound systems (Vivid E9, Vivid S70N, and Vivid E95)

Information about how the reference standard was derived from the dataset (i.e. the "truthing" process): Ground truth annotations of the development and verification datasets were obtained as follows:

- In all Training, Validation, and Verification datasets, annotators performed manual annotation of the contour of the LAA as well as the circumflex and the ridge point of curated images.
- Two cardiologists performed the annotations following US ASE based annotation guidelines and were supervised by 2 US certified clinicians.
- A review panel of three clinical experts provided feedback on the annotations which were corrected (as needed) until a consensus agreement was achieved between the annotators and reviewers.

Description of how independence of verification data from training data was ensured:

- The verification dataset is selected from independent clinical research institutions that have never been used for training and validation (tuning), ensuring the elimination of potential data leakage.

Summary of Clinical Tests:

The subject to this premarket submission, Vivid Pioneer, 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 Pioneer to be as safe, effective, and performs in a substantially equivalent manner as the predicate Vivid E95 (K220882).