December 21, 2018

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

Re: K182750
Trade/Device Name: 4D View
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: September 27, 2018
Received: September 28, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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
Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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 *(if known)*

K182750

Device Name
4D View

Indications for Use *(Describe)*

Image display of GE Ultrasound 3D/4D data sets for diagnostic purposes including measurements on displayed image.

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.

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"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."

510(k) Summary

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

Date:	September 27, 2018
Submitter:	GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC 9900 Innovation Drive Wauwatosa, WI 53226
Primary Contact Person:	Tracey Ortiz Regulatory Affairs Director GE Healthcare T:(262)676-6120
Secondary Contact Person:	Charlotte K. Munthe Jørgensen Senior Regulatory Affairs Leader GE Healthcare Austria GmbH& Co OG
Device Trade Name:	4D View
Common/Usual Name:	PACS / Picture archiving and communications system
Classification Names:	Class II
Product Code:	Picture archiving and communications system, 21 CFR 892.2050, LLZ
Primary Predicate Device(s):	4D View (K131118)
Reference Predicate Device(s):	Voluson E10 (K172342)
Device Description:	Standalone software product with Primary Operating Functions: • Display and editing of GE Ultrasound 3D/4D data sets • Measurements on displayed image incl. derived calculations based on medical literature in the following applications: Abdominal, Obstetrics, Gynecology, Cardiology, Transrectal, Vascular, Cephalic, Small Parts, Pediatrics, Musko-Skeletal (MSK). • Data storage (image, measurement and patient data) • Data transfer to and from remote systems (e.g. via DICOM®1) • Adding annotations to acquired image

Intended Use/ Indication for Use:	Image display of GE Ultrasound 3D/4D data sets for diagnostic purposes including measurements on displayed image.
Technology:	4D View version 18 employs the same fundamental scientific technology as its predicate device.
Determination of Substantial Equivalence:	Comparison to Predicates The proposed 4D View is substantially equivalent to the predicate 4D View (K131118) with regards to intended use, capabilities, technological characteristics, safety and effectiveness. The following is an overview between the proposed 4D View and the predicate 4D View (K131118). • The proposed 4D View and the predicate 4D View software are both picture archiving and communication systems. • The proposed 4D View and the predicate 4D View software have the same clinical applications. • Both software systems devices operate on the same platform. • The proposed 4D View and the predicate 4D View have the same image processing techniques. • The software devices process the same type of images. • The proposed 4D View and the predicate 4D View software device have similar capabilities in terms of performing measurements, capturing digital images, reviewing and reporting studies. • The proposed 4D View and the predicate 4D View software operate with the same main interfaces of connectivity and archiving. • The proposed 4D View adds workflow improvements to already cleared measurement functionality. • The proposed 4D View adds improvements to the already cleared archive and DICOM functionality. The reference predicate, Voluson E10 and 4D View are also similar in that they display ultrasound medical images and utilize DICOM.

Summary of Non-Clinical Tests:

The 4D View and its applications comply with voluntary standards:

1. ISO 14971:2007 - Medical devices - Application of risk management to medical devices
2. NEMA PS 3.1 -3.20 Digital Imaging and Communications in Medicine (DICOM) set
3. IEC 62304:2006 - Medical device software - Software life cycle process

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)

Summary of Clinical Tests:

The subject of this premarket submission, 4D View, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the proposed 4D View to be as safe, as effective, and performance is substantially equivalent to the predicate devices.