GE Medical Systems Ultrasound & Primary Care Diagnostics, LLC
% Tracey Ortiz
Regulatory Affairs Director
9900 Innovation Drive
WAUWATOSA WI 53226

April 17, 2020

Re: K200158
Trade/Device Name: LOGIQ E10
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, ITX, IYO,
Dated: January 21, 2020
Received: January 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) 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

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)*

K200158

Device Name

LOGIQ E10

Indications for Use *(Describe)*

LOGIQ E10 is intended for use by a qualified physician for ultrasound evaluation of Fetal / Obstetrics; Abdominal (including Renal, Gynecology/Pelvic); Pediatric; Small Organ (Breast, Testes, Thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (Adult and Pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including Prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (Abdominal and Vascular).

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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510(k) Summary

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

Date:	January 21, 2020
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC 9900 Innovation Dr Wauwatosa, WI 53226
Manufacturer:	GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC 9900 Innovation Dr Wauwatosa, WI 53226
Primary Contact Person:	Tracey Ortiz Regulatory Affairs Director GE Healthcare T: (262)676-6120
Alternate Contact Person:	Elizabeth Wentworth Regulatory Affairs Specialist GE Healthcare
Device: Trade Name:	LOGIQ E10
Common/Usual Name:	LOGIQ E10
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:	K173555 LOGIQ E10 Diagnostic Ultrasound System
Reference Device(s):	K170445 LOGIQ S8 Diagnostic Ultrasound System K192159 Voluson E10 Diagnostic Ultrasound System K152309 LOGIQ E9 Diagnostic Ultrasound System K161843 Aplio i900/i800/i700 Diagnostic Ultrasound System V2.0 (ATI) K190442 Koios DS for Breast
Device Description:	The LOGIQ E10 is a full featured, track 3, general purpose diagnostic ultrasound system which consists of a mobile console that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized controls, LCD touch screen and color widescreen

monitor. The system utilizes a variety of linear, curved, phased, dual, and matrix array transducers to support the broad imaging capabilities.

Intended Use:

LOGIQ E10 is intended for use by a qualified physician for ultrasound evaluation of Fetal / Obstetrics; Abdominal (including Renal, Gynecology/Pelvic); Pediatric; Small Organ (Breast, Testes, Thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (Adult and Pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including Prostate); Transrectal; Transvaginal; Transesophageal and Intraoperative (Abdominal and Vascular).

Technology:

The LOGIQ E10 employs the same fundamental scientific technology as its predicate device(s).

Determination of Substantial Equivalence:

Comparison to Predicates

The proposed LOGIQ E10 is substantially equivalent to the predicate devices. The following is an overview of the differences between the proposed LOGIQ E10 and the predicate LOGIQ E10 (K173555). The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.

- The LOGIQ E10 and predicate LOGIQ E10 systems have the same clinical intended use, except Intraoperative (Abdominal) that is available on predicate LOGIQ E9 K152309).
- The LOGIQ E10 and predicate LOGIQ E10 systems have the same imaging modes.
- The systems are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The systems have acoustic power levels which are below the applicable FDA limits.
- The LOGIQ E10 and predicate LOGIQ E10 systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The LOGIQ E10 and predicate LOGIQ E10 systems have been designed in compliance with approved electrical and physical safety standards.
- The transducers supported in proposed LOGIQ E10 and predicate LOGIQ E10 are identical except:
  - the following transducers migrated from LOGIQ E9 (K152309): L3-9i-D, 6S-D, C2-6b-D, P6D;
  - the following transducers migrated from LOGIQ S8 (K170455): L3-12-D, BE9CS-D
  - adding a new transducer, L6-24-D, which is similar to the

previously cleared L8-18i-D
- adding B-Flow (hybrid) as a new mode to: C1-6-D, C1-6VN-D, C2-9-D, C2-9VN-D, L2-9-D, L2-9VN-D, L3-12-D, ML6-15-D, L8-18i-D;

- The software features supported in proposed LOGIQ E10 and predicate LOGIQ E10 are identical except:
  - the following software features have been migrated from Voluson E10 (K192195): SonoNT, SonoIT, SonoAVC for renal cyst, SonoRenderLive.
- UGAP is a new feature similar to ATI on Aplio i900/i800/i700 Diagnostic Ultrasound System V2.0 (K161843) that measures the attenuation value in the liver.
- Other minor software feature modifications are: improved the Vnav image based registration, enabled Device Management, add a type 2 to SRI-HD

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 LOGIQ E10 and its applications comply with voluntary standards:

- AAMI/ANSI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/(R)2012 And A1:2012
- 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, 2015
- ISO 10993-1, Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing Within A Risk Management Process, 2009
- 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

FDA Guidance's used:

- Off-The-Shelf Software Use in Medical Devices - Guidance for Industry and Food and Drug Administration Staff – Issued on September 27, 2019
- Marketing Clearance of Diagnostic Ultrasound Systems and Transducer- Guidance for Industry and Food and Drug Administration Staff Document – Issued on June 27, 2019
- Guidance for Industry and Food and Drug Administration Staff, Content of Premarket Submissions for Management of Cybersecurity in Medical Devices – Issues on October 2, 2014
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices – Issued on May 11, 2005
- Guidance for Industry – Cyber Security for Networked Medical Devices Containing Off-The-Shelf (OTS) Software issued January 14, 2005

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 materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ E10, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ E10 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).