GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC
% Mr. Bryan Behn
Regulatory Affairs Director
9900 Innovation Drive
WAUWATOSA WI 53226

January 8, 2021

Re: K203114
Trade/Device Name: LOGIQ P10, LOGIQ P9, LOGIQ P8
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: October 14, 2020
Received: October 15, 2020

Dear Mr. Behn:

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)*
K203114

Device Name
LOGIQ P10, LOGIQ P9, LOGIQ P8

Indications for Use *(Describe)*
The LOGIQ P10, LOGIQ P9, LOGIQ P8 are general purpose diagnostic ultrasound system intended for use by a qualified and trained healthcare professional physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The LOGIQ P10, LOGIQ P9 and LOGIQ P8 clinical applications include: evaluation of Fetal/Obstetrics; Abdominal; 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, vascular).

Modes of operation include: B, M, PW, Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded pulse, 3D/4D Imaging mode, Elastography, Shear Wave Elastography, Attenuation Imaging and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD.
The LOGIQ P10, LOGIQ P9 and LOGIQ P8 are intended to be used in a hospital or medical clinic.

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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Section 5: 510(k) Summary K203114

LOGIQ P10, LOGIQ P9 and LOGIQ P8

510(k) Summary K203114

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

Date:	October 14, 2020
Submitter:	GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC 9900 Innovation Dr Wauwatosa, WI 53226
Manufacturer:	GE Ultrasound Korea, Ltd. 9, Sunhwan-ro 214 beon-gil, Jungwon-gu, Seongnam-si, Gyeonggi-do, Republic of Korea
Primary Contact Person:	Bryan Behn Regulatory Affairs Director GE Healthcare T:(262)-247-5502
Alternate Contact Person:	Chae-Rin, Song Regulatory Affairs Specialist GE Healthcare GE Ultrasound Korea, Ltd. T: +82-31-740-6310
Device: Trade Name:	LOGIQ P10, LOGIQ P9 and LOGIQ P8
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:	K181783 LOGIQ P9/P7 Diagnostic Ultrasound System
Reference Predicate Device(s):	K170445 LOGIQ S8 Diagnostic Ultrasound System K180535 Voluson P6 Voluson P8 K173555 LOGIQ E10, K200119 LOGIQ E10s
Device Description:	The LOGIQ P10, LOGIQ P9 and LOGIQ P8 are full featured, Track 3 device, primarily intended for general purpose diagnostic ultrasound system which consists of a mobile console approximately 55 cm wide, 74 cm deep and 160 cm high that provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, specialized

	controls, 10.4-inch LCD touch screen and color 23.8-inch LCD image display.
Indications for Use:	The LOGIQ P10, LOGIQ P9, LOGIQ P8 are general purpose diagnostic ultrasound system intended for use by a qualified and trained healthcare professional physician for ultrasound imaging, measurement, display and analysis of the human body and fluid. The LOGIQ P10, LOGIQ P9 and LOGIQ P8 clinical applications include: evaluation of Fetal/Obstetrics; Abdominal; 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, vascular). Modes of operation include: B, M, PW, Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded pulse, 3D/4D Imaging mode, Elastography, Shear Wave Elastography, Attenuation Imaging and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD. The LOGIQ P10, LOGIQ P9 and LOGIQ P8 are intended to be used in a hospital or medical clinic.
Technology:	The LOGIQ P10, LOGIQ P9 and LOGIQ P8 employs the same fundamental scientific technology as its predicate devices.
Determination of Substantial Equivalence:	Comparison to Predicates The proposed LOGIQ P10, LOGIQ P9 and LOGIQ P8 systems are substantially equivalent to the predicate devices. The following is an overview of the differences between the proposed LOGIQ P10, LOGIQ P9 and LOGIQ P8 and the predicate LOGIQ P9 and LOGIQ P7(K181783). • The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis. • The LOGIQ P10/P9/P8 and predicate LOGIQ P9/P7 systems have the same clinical intended uses. • The LOGIQ P10/P9/P8 and predicate LOGIQ P9/P7 systems have the similar imaging modes. LOGIQ P10, LOGIQ P9 and LOGIQ P8 have additional UGAP mode cleared in LOGIQ E10s(K200119). • The LOGIQ P9/P7 and predicate LOGIQ P9/P7 systems transducers are identical except for the addition of 5 new transducers C1-6-D, C3-10-D, C2-7-D, M5Sc-RS, 10C-D. C1-6-D, C3-10-D, C2-7-D have been migrated from LOGIQ E10s(K200119), M5Sc-RS has been migrated

from Vivid iq and 10C-D has been migrated from LOGIQ S8(K170445).

- The LOGIQ P10/P9/P8 and predicate LOGIQ P9/P7 systems have the same indications for use with the addition of Obstetric exams
- 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 PO10/P9/P8 and predicate LOGIQ P9/P7 systems have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The LOGIQ P10/P9/P8 and predicate LOGIQ P9/P7 systems have been designed in compliance with approved electrical and physical safety standards.
- The software features supported in proposed LOGIQ P10/P9/P8 and predicate LOGIQ P9/P7 are identical except:
  - UGAP is migrated from LOGIQ E10s K200119 that measures the attenuation value in the liver.
  - SonoNT, SonoIT, Sono AVC for Renal have been migrated from Voluson E10(K192159)

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 to applicable medical device safety standards. The LOGIQ P10, LOGIQ P9 and LOGIQ P8 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
- IEC60601-1-2, Medical Electrical Equipment – Part 1-2:General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbance - Requirements and Tests, Edition 4.0, 2014
- IEC60601-2-37, Medical Electrical Equipment – Part 2-37:Particular Requirements for the Safety of Ultrasonic

Medical Diagnostic and Monitoring Equipment, Edition 2.1, 2015ISO10993-1, Biological Evaluation of Medical Devices- Part 1: Evaluation and Testing- Third Edition, 2009

- ISO14971, Application of risk management to medical devices: Second edition 2007
- NEMA PS 3.1 - 3.20 (2016), Digital Imaging and Communications in Medicine (DICOM) Set. (Radiology)
- 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)
- Safety testing (Verification)

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, LOGIQ P10, LOGIQ P9 and LOGIQ P8, did not require clinical studies to support substantial equivalence.

Conclusion: GE Healthcare considers the LOGIQ P10, LOGIQ P9 and LOGIQ P8 to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).