December 7, 2023

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

Re: K232381
Trade/Device Name: LOGIQ Totus
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, IYO, ITX, QIH
Dated: November 16, 2023
Received: November 16, 2023

Dear Bryan 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 (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.

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K232381

Device Name
LOGIQ Totus

Indications for Use *(Describe)*

The LOGIQ Totus is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid. LOGIQ Totus clinical applications include: 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.

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, Contrast, Enhanced Imaging and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD.

The system is intended to be used in Hospital or Clinical environments such as Intensive Care Unit(ICU, CVICU, CCU), Neonatal Intensive Care Unit(NICU), Pediatric Intensive Care Unit(PICU), Emergency Room, Operating Room, Outpatient Surgery Clinic, Radiology, Medical Office(Nurse Practitioner), Observational Units, Cath Lab, Clinic, Physician's Office, Labor/Deliver Unit and Oncology.

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 **K232381**

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

Date:	Dec 5, 2023
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 13204, 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 Leader GE Healthcare GE Ultrasound Korea, Ltd. T: +82-31-740-6310
Device: Trade Name:	LOGIQ Totus
Common/Usual Name:	Diagnostic Ultrasound System
Classification Names:	Class II
Product Code:	IYN(primary), IYO, ITX, QIH (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, 21CFR 892.2050
Primary Predicate Device:	**K211524** LOGIQ E10s, LOGIQ Fortis Diagnostic Ultrasound System
Reference Predicate Device(s):	**K202035** Vscan Air **K200743** Vivid E80/Vivid E90/Vivid E95 R4
Device Description:	The LOGIQ Totus is full featured, Track 3 device, primarily intended for general purpose diagnostic ultrasound system which consists of a mobile console approximately 490mm wide(monitor width: 545mm), 835mm deep and 1415~1815mm high that provides digital acquisition, processing and display capability.

	The user interface includes a computer keyboard, specialized controls, 14-inch LCD touch screen and color 23.8-inch LCD & HDU image display.
Indications for Use:	The LOGIQ Totus is a general-purpose diagnostic ultrasound system intended for use by qualified and trained healthcare professionals for ultrasound imaging, measurement, display and analysis of the human body and fluid. LOGIQ Totus clinical applications include: 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. 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, Contrast Enhanced Imaging and Combined modes: B/M, B/Color, B/PWD, B/Color/PWD, B/Power/PWD. The system is intended to be used in Hospital or Clinical environments such as Intensive Care Unit(ICU, CVICU, CCU), Neonatal Intensive Care Unit(NICU), Pediatric Intensive Care Unit(PICU), Emergency Room, Operating Room, Outpatient Surgery Clinic, Radiology, Medical Office (Nurse Practitioner), Observational Units, Cath Lab, Clinic, Physician's Office, Labor/Deliver Unit and Oncology.
Technology:	The LOGIQ Totus employs the same fundamental scientific technology as its predicate devices.
Determination of Substantial Equivalence:	The proposed LOGIQ Totus systems is substantially equivalent to the predicate LOGIQ E10s and LOGIQ Fortis(K211524) with regards to intended use, imaging capabilities, technological characteristics, imaging modes, hardware, and safety effectiveness. The system is all intended for diagnostic ultrasound imaging and fluid flow analysis. The Proposed LOGIQ Touts and the predicate LOGIQ E10s and LOGIQ Fortis(K211524) have the same

clinical intended use except Transesophageal and Intraoperative(Abdominal, Vascular). LOGIQ Totus doesn't include both clinical applications.

The proposed LOGIQ Totus and the predicate LOGIQ E10s and LOGIQ Fortis(K211524) have the same imaging modes.

The proposed LOGIQ Totus are manufactured with materials which have been evaluated and found to be safe for the intended use of the device.

The proposed LOGIQ Totus have acoustic power levels which are below the applicable FDA limits.

The proposed LOGIQ Totus and the predicate LOGIQ E10s and LOGIQ Fortis(K211524) have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.

The proposed LOGIQ Totus have been designed in compliance with approved electrical and physical safety standards.

The following is an overview of the differences between the proposed LOGIQ Totus and the predicate LOGIQ E10s, LOGIQ Fortis(K211524).

Probes:

The probes supported in prosed LOGIQ Totus and the predicate LOGIQ E10s, LOGIQ Fortis(K211524) are identical except;

- Addition
  - 9S-D (migrated from Vivid E80/E90/E95 R4 K200743)
  - 12S-D (migrated from Vivid E80/E90/E95 R4 K200743)

Software:

The software features supported in proposed LOGIQ Totus and the predicate LOGIQ E10s, LOGIQ Fortis(K211524) are similar except:

- Auto Preset Selection
- Auto Abdominal Color Assistant

- Vscan Air CL Support
- VITA on demand
- Auto EF/AFI Enhancement

Compatible device:

Addition of Vscan Air CL, WiFi SUB for Vscan Air CL and Wireless Charger

AI Testing Summary:

- Auto preset selection:

Summary test statics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance	· The overall model success rate of the Abdomen, Air, Breast, Carotid, Leg, MSK, Scrotal, Thyroid and Carotid/Thyroid(Mixed) view suggestion is expected to be 80% or higher. · The number of individual patient's images were collected from: 50+ patients · The number of samples, if different from above, and the relationship between the two: 330+ images
Information about clinical subgroups and confounders present in the dataset	· Gender: Male & Female · Age: Reproductive age, specific age not collected. · Ethnicity/Country; USA(57%) and Australia(43%)
Information about equipment and protocols used to collect images	Mix of data from across 4 different probe models with LOGIQ Totus console. The data collection protocol was standardized across all data

	collection sites.
Information about how the reference standard was derived from the dataset(i.e. the “truthing” process)	For the testing process, the results are generated by the AI software and the same are verified as Pass or Fail by a certified sonographer/clinician. The results are then aggregated to yield an accuracy metric for the AI algorithm.
Description of how independence of test data from training data was ensured	The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two.

- Auto Abdominal Color Assistant:

Summary test statistics or other test results including acceptance criteria or other information supporting the appropriateness of the characterized performance	· The overall model success rate of the Aorta, Kidney, Liver, GB and Pancreas view suggestion is expected to be 80% or higher. · The number of individual patients’ images were collected from: 40 patients. · The number of samples, if different from above, and the relationship between the two: 280+ images
Information about clinical subgroups and confounders present in the dataset	· Gender: Male & Female · Age: Reproductive age, specific age not collected. · Ethnicity/country: USA(35%) and Australia(65%)
Information about equipment and protocols used to	Mix of data from across 4 different probe models with LOGIQ Totus console. The

collect images	data collection protocol was standardized across all data collection sites.
Information about how the reference standard was derived from the dataset(i.e. the “truthing” process)	For the testing process, the results are generated by the AI software and the same are verified a Pass or Fail by a certified sonographer / clinician. The results are then aggregated to yield an accuracy metric for the AI algorithm.
Description of how independence of test data from training data was ensured	The exams used for test/training validation purpose are separated from the ones used during training process and there is no overlap between the two.

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 Totus and its applications comply with voluntary standards:

- ANSI AAMI ES60601-1, Medical Electrical Equipment – Part 1: General Requirements for Safety, 2005/(R)2012 And A1:2012, C1:2009/(R)2012 & A2:2010/(R)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, 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 A Risk Management Process, Fifth edition, 2018
- ISO 14971, Medical devices - Application of risk management to medical device, 2019
- 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
- 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 materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

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

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