GE Medical Systems Ultrasound and Primary Care Diagnostics, LLC June 11, 2020
GE Healthcare
% Ms. Tracey Ortiz
Regulatory Affairs Director
9900 W. Innovation Drive
WAUWATOSA WI 53226

Re: K200998
Trade/Device Name: Versana Active
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: April 14, 2020
Received: April 16, 2020

Dear Ms. 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)*

K200998

Device Name

Versana Active

Indications for Use *(Describe)*

The Versana Active 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.
Versana Active clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Urology, Pediatric, Small Organ (includes breast, testes, thyroid), Neonatal Cephalic, Adult Cephalic, Cardiac (includes Adult and Pediatric), Vascular/ Peripheral Vascular, Musculoskeletal Conventional, Musculoskeletal Superficial, Thoracic/ Pleural, Transcranial, Transrectal, Transvaginal, Interventional guidance (includes tissue biopsy, fluid drainage, vascular and non-vascular access).
Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse, 3D, 4D and Combined modes: B/M, B/ Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD or CWD.
The device is intended for use in an indoor hospital environment, in medical offices/clinics and other Healthcare facilities.

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 K200998

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

Date: April 14, 2020

Submitter: GE Medical Systems Ultrasound and Primary Care Diagnostics
9900 Innovation Drive
Wauwatosa, WI 53226

Primary Contact Person: Tracey Ortiz
Regulatory Affairs Director
GE Healthcare
T:(262)676-6120

Secondary Contact Person: Gao Ju
Regulatory Affairs
GE Healthcare

Device Trade Name: Versana Active

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: Versana Active (K191798)

Secondary Predicate Device(s): Versana Balance (K191792)

Device Description:

The Versana Active is a general purpose, Track 3, diagnostic ultrasound system for use by qualified and trained healthcare professionals. The Versana Active is a compact, portable system, the device includes operator control panel, display monitor and transducers.

The system provides digital acquisition, processing and display capability.

The system can be powered through an electrical wall outlet for long term use or from internal battery for a short time use.

The operator control panel includes function keys, trackball and an alfa-numeric keyboard as input sources of the device.

The Versana Active design enables the system to be attached to three kinds of optional mobile carts.

The variety of transducers include convex, linear, sector and mechanical 4D. The access types include trans- body surface, transrectal, transvaginal and transcranial.

Data can be imported or exported by DVD, USB, LAN or WiFi if the USB wireless adapter is connected to the system. An external ECG module has been verified to use as input for gating/triggering during scanning.
The system has a HDMI port connection and with the use of optional Video Output Adapter, the system can have a Composite Out port connection and a S-Video Out port connection. An optional spare battery charger allows the system battery to be charged externally. The system has an option for an external Printer USB Isolator for printers to connect. The system supports one way, Bluetooth communication capability from the system to a personal device to allow for sharing of the patient's data/images when the Bluetooth USB adapter is connected to the system.

Intended Use: The Versana Active 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.
Versana Active clinical applications include: Fetal/Obstetrics, Abdominal, Gynecology, Urology, Pediatric, Small Organ (includes breast, testes, thyroid), Neonatal Cephalic, Adult Cephalic, Cardiac (includes Adult and Pediatric), Vascular/Peripheral Vascular, Musculoskeletal Conventional, Musculoskeletal Superficial, Thoracic/ Pleural, Transcranial, Transrectal, Transvaginal, Interventional guidance (includes tissue biopsy, fluid drainage, vascular and non-vascular access).
Modes of operation include: B, M, PW Doppler, CW Doppler, Color Doppler, Color M Doppler, Power Doppler, Harmonic Imaging, Coded Pulse, 3D, 4D and Combined modes: B/M, B/ Color M, B/PWD or CWD, B/Color/PWD or CWD, B/Power/PWD or CWD.
The device is intended for use in an indoor hospital environment, in medical offices/clinics and other Healthcare facilities.

Technology: The Versana Active employs the same fundamental scientific technology as its predicate devices.

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The proposed Versana Active system is substantially equivalent to the predicate Versana Active device (K191798) with regard to intended use, imaging capabilities, technological characteristics and safety effectiveness.

- The proposed Versana Active and predicate Versana Active (K191798) have similar clinical indications for use.
- RAB2-6-RS transducer, which was cleared in predicate Versana Balance (K191792), is being added to the proposed Versana Active. The RAB2-6-RS transducer supports the same applications and modes as the RAB2-6-RS that was cleared in predicate Versana Balance (K191792).
- The proposed Versana Active and predicate Versana Active (K191798) have similar imaging modes. 3D and 4D Imaging modes are being added for the use with RAB2-6-RS transducer, which were cleared in predicate Versana Balance (K191792).
- The biopsy guide is being added for RAB2-6-RS transducer. The biopsy guide is the same as the biopsy guide used with RAB2-6-RS transducer in predicate Versana Balance (K191792).
- TUI (Tomographic Ultrasound Imaging) feature is being added, which has already been cleared in predicate Versana Balance (K191792).
- Adding new hardware options:
  - Two addition mobile cart options.
  - Video Output Adapter, which allows HDMI signal to be transferred to S-video and CVBS video signal.
  - Spare Battery Charger, which allows battery to be charged out from system.

Summary of Non-Clinical Tests:

Versana Active 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 comply with applicable medical device safety standards. The Versana Active complies with voluntary standards:

- ANSI/AAMI ES60601-1, Medical Electrical Equipment – Part 1: General requirements for basic safety and essential performance - 2005/(R)2012 and A1:2012, C1:2009/(R)2012 and 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 disturbances - Requirements and tests - Edition 4.0, 2014

- IEC 60601-2-37, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance 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 - Fourth edition, 2009
- ISO 14971, Application of risk management to medical devices - 2007
- 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, 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 material and other patient contact materials are biocompatible.

Summary of Clinical Tests:

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

Conclusion: GE Healthcare considers the Versana Active to be as safe, as effective, and performance is substantially equivalent to the predicate devices.