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

November 21, 2018

Re: K182277
Trade/Device Name: Versana Premier
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic Pulsed Doppler Imaging System
Regulatory Class: Class II
Product Code: IYN, ITX, IYO
Dated: November 10, 2018
Received: November 13, 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)*

K182277

Device Name
Versana Premier

Indications for Use *(Describe)*

The Versana Premier are general purposed ultrasound imaging and analysis systems providing digital acquisition, processing and display capability and clinical applications including: Fetal/Obstetrics, Abdominal (includes GYN and Urological/Prostate), Pediatric, Small Organ (includes breast, testes, thyroid), Cardiac, Peripheral Vascular, Musculos-keletal Conventional, Musculos-keletal Superficial, Transcranial, Transrectal, Transvaginal, Tissue Biopsy/Fluid Drainage.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."

Indications for Use Forms

The following forms represent indications with clinical applications and exam types along with the modes of operation for the Versana Premier. Combinations identified "P" represents those previously cleared with another GE Ultrasound system. Combinations identified as "N" are new.

The following Indication for Use forms are appended:

System: Versana Premier
Transducer: 4C-RS
Transducer: 8C-RS
Transducer: 3Sc-RS
Transducer: L6-12-RS
Transducer: E8C-RS
Transducer: RAB2-6-RS
Transducer: 6S-RS
Transducer: L8-18i-RS
Transducer: E8Cs-RS
Transducer: BE9Cs-RS
Transducer: 12L-RS
Transducer: 12S-RS
Transducer: LK760-RS
Transducer: RIC5-9A-RS

GE Versana Premier Ultrasound System

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	**[5][8]**
Abdominal[1]	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	**[5][6][8]**
Pediatric	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**[8]**
Small Organ [2]	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	**[6][8]**
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**[8]**
Peripheral Vascular	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	**[8]**
Musculo-skeletal Conventional	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	**[8]**
Musculo-skeletal Superficial	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	**[8]**
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**	**N**		
Transesophageal											
Transrectal	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	**[8]**
Transvaginal	**N**	**N**	**N**		**N**		**N**	**N**	**N**	**N**	**[8]**
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	**N**	**N**	**N**		**N**	**N**	**N**	**N**	**N**	**N**	**[8]**
Vascular Access[7]	**N**		**N**		**N**		**N**	**N**	**N**	**N**	**[8]**
Non-vascular access	**N**							**N**	**N**	**N**	**[8]**

N = new indication;

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with 4C-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	**[8]**
Abdominal[1]	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	**[6][8]**
Pediatric	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**P**	
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	**P**				**P**		**P**	**P**	**P**	**P**	**[8]**
Vascular Access[7]											
Non-vascular access	**N**							**N**	**N**	**N**	**[8]**

N = new indication; P= previously cleared by FDA K160277; P1= previously cleared by FDA K163596; P2= previously cleared by FDA K151028; P3= previously cleared by FDA K161706, P4= previously cleared by FDA K160078

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonic

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with 8C-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	
Peripheral Vascular											
Musculo-skeletal Conventional	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]											
Vascular Access[7]											
Non-vascular access											

N = new indication; P= previously cleared by FDA K160277; P[1]= previously cleared by FDA K163596; P[2]= previously cleared by FDA K151028; P[3]= previously cleared by FDA K161706, P[4]= previously cleared by FDA K160078

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with 3Sc-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	**P**	**P**	**P**		**P**		**P**	**P**	**P**		
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**		
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	**P**	**P**	**P**	**P[1]**	**P**	**P**	**P**	**P**	**P**		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial	**P**	**P**	**P**	**P[3]**	**P**	**P**	**P**	**P**	**P**		
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	**P**				**P**		**P**	**P**	**P**		**[8]**
Vascular Access[7]											
Non-vascular access											

N = new indication; P= previously cleared by FDA K160277; P[1]= previously cleared by FDA K163596;

P[2]= previously cleared by FDA K151028; P[3]= previously cleared by FDA K161706, P[4]= previously cleared by FDA K160078

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with L6-12-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric	**P**		**P**		**P**		**P**	**P**	**P**	**P**	**[8]**
Small Organ [2]	**P**		**P**		**P**		**P**	**P**	**P**	**P**	**[6][8]**
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	**P**		**P**		**P**		**P**	**P**	**P**	**P**	**[8]**
Musculo-skeletal Conventional	**P**		**P**		**P**		**P**	**P**	**P**	**P**	**[8]**
Musculo-skeletal Superficial	**P**		**P**		**P**		**P**	**P**	**P**	**P**	**[8]**
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance[4]											
Tissue Biopsy/Fluid Drainage[4]	**P**				**P**		**P**	**P**	**P**	**N**	**[8]**
Vascular Access[7]	**N**				**N**		**N**	**N**	**N**	**N**	**[8]**
Non-vascular access	**N**							**N**	**N**	**N**	**[8]**

N = new indication; P= previously cleared by FDA K160277; P[1]= previously cleared by FDA K163596; P[2]= previously cleared by FDA K151028; P[3]= previously cleared by FDA K161706, P[4]= previously cleared by FDA K160078

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with E8C-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	**[8]**
Abdominal[1]	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	**[8]**
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	**[8]**
Transvaginal	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	**[8]**
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	**P**				**P**		**P**	**P**	**P**	**N**	
Vascular Access[7]											
Non-vascular access											

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P[2]= previously cleared by FDA K151028; P[3]= previously cleared by FDA K161706, P[4]= previously cleared by FDA K160078

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with RAB2-6-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	**[5][8]**
Abdominal[1]	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	**[5][8]**
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	**P**				**P**	**P**	**P**	**P**	**P**	**N**	**[8]**
Vascular Access[7]											
Non-vascular access											

N = new indication; P= previously cleared by FDA K160277; P[1]= previously cleared by FDA K163596;

P[2]= previously cleared by FDA K151028; P[3]= previously cleared by FDA K161706, P[4]= previously cleared by FDA K160078

Notes: [1] Abdominal includes GYN and Urological/Prostate;
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[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
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[◗] Coded Pulse is for digitally encoded harmonics

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with 6S-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**		**[8]**
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**		**[8]**
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**	**P**		
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]											
Vascular Access[7]											
Non-vascular access											

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[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with L8-18i-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ [2]	**P**	**P**	**P**		**P**		**P**	**P**	**P**		**[8]**
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	**P**	**P**	**P**		**P**		**P**	**P**	**P**		**[8]**
Musculo-skeletal Conventional											
Musculo-skeletal Superficial	**P**	**P**	**P**		**P**		**P**	**P**	**P**		**[8]**
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]											
Vascular Access[7]											
Non-vascular access											

N = new indication; P= previously cleared by FDA K160277; P[1]= previously cleared by FDA K163596;

P[2]= previously cleared by FDA K151028; P[3]= previously cleared by FDA K161706, P[4]= previously cleared by FDA K160078

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with E8Cs-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	
Abdominal[1]	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	**[6][8]**
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	**[8]**
Transvaginal	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	**[8]**
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	**P**	**P**	**P**		**P**		**P**	**P**	**P**	**N**	
Vascular Access[7]											
Non-vascular access											

N = new indication; P= previously cleared by FDA K160277; P[1]= previously cleared by FDA K163596;

P[2]= previously cleared by FDA K151028; P[3]= previously cleared by FDA K161706, P[4]= previously cleared by FDA K160078

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with BE9CS-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]	**P**	**P**	**P**		**P**		**P**	**P**	**P**		**[8]**
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal	**P**	**P**	**P**		**P**		**P**	**P**	**P**		**[8]**
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	**P**	**P**	**P**		**P**		**P**	**P**	**P**		
Vascular Access[7]											
Non-vascular access											

N = new indication; P= previously cleared by FDA K160277; P[1]= previously cleared by FDA K163596;

P[2]= previously cleared by FDA K151028; P[3]= previously cleared by FDA K161706, P[4]= previously cleared by FDA K160078

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with 12L-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric	**P1**		**P1**		**P1**		**P1**	**P1**	**P1**	**P1**	**[8]**
Small Organ [2]	**P1**		**P1**		**P1**		**P1**	**P1**	**P1**	**P1**	**[6][8]**
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular	**P1**		**P1**		**P1**		**P1**	**P1**	**P1**	**P1**	**[8]**
Musculo-skeletal Conventional	**P1**		**P1**		**P1**		**P1**	**P1**	**P1**	**P1**	**[8]**
Musculo-skeletal Superficial	**P1**		**P1**		**P1**		**P1**	**P1**	**P1**	**P1**	**[8]**
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	**P2**				**P2**		**P2**	**P2**	**P2**	**P2**	**[8]**
Vascular Access[7]	**P2**		**P2**		**P2**		**P2**	**P2**	**P2**	**P2**	**[8]**
Non-vascular access	**N**							**N**	**N**	**N**	**[8]**

N = new indication; P= previously cleared by FDA K160277; P1= previously cleared by FDA K163596; P2= previously cleared by FDA K151028; P3= previously cleared by FDA K161706, P4= previously cleared by FDA K160078

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with 12S-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**	**P[1]**		**[8]**
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]	**P[4]**	**P[4]**	**P[4]**	**P[4]**	**P[4]**	**P[4]**	**N**	**P[4]**	**P[4]**		**[8]**
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial	**P[3]**	**P[3]**	**P[3]**	**P[3]**	**P[3]**	**P[3]**	**P[3]**	**P[3]**	**P[3]**		
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]											
Vascular Access[7]											
Non-vascular access											

N = new indication; P= previously cleared by FDA K160277; P[1]= previously cleared by FDA K163596;

P[2]= previously cleared by FDA K151028; P[3]= previously cleared by FDA K161706, P[4]= previously cleared by FDA K160078

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with LK760-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics											
Abdominal[1]											
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional	**P²**		**P²**		**P²**		**P²**	**P²**	**P²**	**N**	
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal											
Transvaginal											
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]											
Vascular Access[7]											
Non-vascular access											

N = new indication; P= previously cleared by FDA K160277; P¹= previously cleared by FDA K163596;

P²= previously cleared by FDA K151028; P³= previously cleared by FDA K161706, P⁴= previously cleared by FDA K160078

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Versana Premier with RIC5-9A-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application	Mode of Operation										
	B	M	Doppler Modes					Combined Modes*	Harmonic Imaging	Coded Pulse◗	Other
			PW	CW	Color	Color M	Power				
Anatomy/Region of Interest											
Ophthalmic											
Fetal / Obstetrics	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	[5][8]
Abdominal[1]	**P[1]**	**P[1]**	**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	[5][8]
Pediatric											
Small Organ [2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural											
Other											
Exam Type, Means of Access											
Transcranial											
Transesophageal											
Transrectal	**N**		**N**		**N**		**N**	**N**	**N**		
Transvaginal	**P[1]**		**P[1]**		**P[1]**		**P[1]**	**P[1]**	**P[1]**	**P[1]**	
Intraoperative											
Interventional Guidance											
Tissue Biopsy/Fluid Drainage[4]	**N**				**N**	**N**	**N**	**N**	**N**	**N**	
Vascular Access[7]											
Non-vascular access											

N = new indication; P= previously cleared by FDA K160277; P[1]= previously cleared by FDA K163596;

P[2]= previously cleared by FDA K151028; P[3]= previously cleared by FDA K161706, P P[4]= previously cleared by FDA K160078

Notes: [1] Abdominal includes GYN and Urological/Prostate;
[2] Small Organ includes breast, testes, thyroid;
[3] Cardiac includes Adult and Pediatric;
[4] Interventional Guidance Tissue Biopsy is 2D biopsy guide
[5] 3D/4D imaging Mode
[6] Elastography imaging-Elasticity
[7] Vascular Access includes intravenous, intra-arterial, central and peripheral lines, upper extremity;
[8] Image guidance for freehand needle/catheter placement;
[*] Combined modes are B/M, B/ Color M, B/PWD, B/Color/PWD, B/Power/PWD;
[◗] Coded Pulse is for digitally encoded harmonics

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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

510(k) Summary

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

Date:	August17, 2018
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 tracey.ortiz@ge.com
Secondary Contact Person:	Gao Gan Regulatory Affairs GE Healthcare
Device Trade Name:	Versana Premier
Common/Usual Name:	Diagnostic Ultrasound System
Classification Names:	Class II
Product Code:	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:	LOGIQ F8 Expert (K160277)
Secondary Predicate Device(s):	LOGIQ P9 (K163596) LOGIQ e (K151028) Vscan Extend (K180995) Predicates used only for changes to transducer applications: Vivid iq (K161706) and Vivid T8 (K160078)
Device Description:	The Versana Premier is a general purpose, diagnostic ultrasound system for use by qualified healthcare professionals. The system consists of a mobile console, operator control panel, display monitor and some transducers. The console provides digital acquisition, processing and display capability. The system has an internal battery to allow for acquisition while the system is not plugged into a power source. The operator control panel includes an ultrasound keyboard, trackball, an alfa-numeric keyboard and a touch panel as input sources of the device.

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

Intended Use: The Versana Premier are general purposed ultrasound imaging and analysis systems providing digital acquisition, processing and display capability and clinical applications including: Fetal/Obstetrics, Abdominal (includes GYN and Urological/Prostate), Pediatric, Small Organ (includes breast, testes, thyroid), Cardiac, Peripheral Vascular, Musculos-keletal Conventional, Musculos-keletal Superficial, Transcranial, Transrectal, Transvaginal, Tissue Biopsy/Fluid Drainage.

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

Determination of Substantial Equivalence:

Comparison to Predicate Devices

The Versana Premier system is a new platform substantially equivalent to the predicate devices. The following is an overview of the differences between the proposed Versana Premier and the predicates LOGIQ F8 Expert (K160277). The systems are all intended for diagnostic ultrasound imaging and fluid flow analysis.

- The Versana Premier and predicate LOGIQ F8 Expert (K160277) have same clinical indications for use.
- The Versana Premier and predicate LOGIQ F8 Expert (K160277) have similar imaging modes.
- The Versana Premier and predicate LOGIQ F8 Expert (K160277) systems transducers are similar. Coded Pulse mode is added to 8C-RS, E8C-RS, RAB2-6-RS, E8Cs-RS transducers. Non-vascular access application is added to 4C-RS transducer. Vascular access and Non-vascular access are added to L6-12-RS transducer. The RIC5-9A-RS transducer is added to Versana Premier which was cleared in LOGIQ P9 (K163596) andhe applications of Transrectal, Tissue Biopsy/Fluid Drainage are being added. The Versana Premier includes the 12L-RS transducer which was cleared in LOGIQ P9 (K163596) however Coded Pulse mode and Non-vascular access are being added. The Versana Premier includes the LK760-RS transducer which was cleared in LOGIQ e (K151028) and Coded Pulse mode is being added. The Versana Premier includes the 12S-RS transducer which was

cleared in LOGIQ P9 (K163596) and Power Doppler Imaging mode is being added. The applications of Cardiac is being added per Vivid T8 (K160078) and Transcranial is being added per Vivid iq (K161706) to the 12S-RS.

- Features added from LOGIQ P9 (K163596): Vocal, Breast Productivity, Thyroid productivity, Tissue Velocity M Mode image (TVM).
- Features added from LOGIQ e (K151028): Needle recognition and Follow-Up tool.
- Features added from Vscan Extend (180995): Auto Bladder Volume and Tricefy Uplink.
- Adding new features called Breast Care 2.0 and Whizz.
- Adding some new hardware
- The Versana Premier and predicate LOGIQ F8 Expert (K160277) have similar capability in terms of performing measurements, capturing digital images, reviewing and reporting studies.
- The system is manufactured with materials which have been evaluated and found to be safe for the intended use of the device.
- The system has acoustic power levels which are below the applicable FDA limits.
- The Versana Premier and predicate LOGIQ F8 Expert (K160277) have been designed in compliance with approved electrical and physical safety standards.

Summary of Non-Clinical Tests:

Versana Premier 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 Premier complies with voluntary standards:

- AAMI/ANSI 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
- IEC60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic

disturbances - Requirements and tests - Edition 4.0 2014-02

- IEC60601-2-37, 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
- ISO10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process - Fourth edition 2009-10-15
- NEMA UD 2, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment – revisions 3 - 2004 (R2009)
- ISO14971, Application of risk management to medical devices, 2007
- NEMA PS 3.1 - 3.20, Digital Imaging and Communications in Medicine (DICOM) Set - 3.1 - 3.20 (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 Premier, did not require clinical studies to support substantial equivalence.

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