



JUN 11 1999

K991842

## GE Vingmed Ultrasound

### Summary of Safety and Effectiveness

Prepared in accordance with 21 CFR Part 807.92(c).

Section a):

1. Submitter: GE Vingmed Ultrasound A/S  
P.O. Box 141,  
N-3191 Horten, Norway  
  
Contact Person: Paul Fredriksen,  
Quality Assurance Manager  
Telephone: 011-47-3302-1107, Fax: 011-47-3302-1350  
  
Date Prepared: 25 February 1999
2. Device Name: GE Vingmed System FiVe Diagnostic Ultrasound System / EchoPac with Strain Rate Imaging Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
3. Marketed Device: GE Vingmed Ultrasound System FiVe diagnostic ultrasound system / EchoPac, 510(k) Number K963315, currently in commercial distribution.
4. Device Description: Strain Rate Imaging is a modification to the motion analysis capability of the System FiVe / EchoPac. It gives the user the ability to assess the rate of deformation in tissue. When used for cardiac analysis, the user can assess the rate of dimensional changes in the myocardium during the cardiac cycle in a manner similar to tissue velocity imaging. Strain rate can also describe the resistance of tissue objects to external compression.
5. Indications for Use: System FiVe is intended for the following applications: Abdominal, Cardiac, Small Organ, Pediatric, Fetal, Intra-Operative, Transesophageal, Transvaginal, Transrectal, Peripheral Vascular, Neonatal and Adult Cephalic.
6. Comparison with Predicate Device: The GE Vingmed System FiVe Diagnostic Ultrasound System / EchoPac with Strain Rate Imaging is of a comparable type and substantially equivalent to the currently marketed GE Vingmed System FiVe / EchoPac. It has the same technological characteristics, is comparable in key safety and effectiveness features, uses the same design, construction, and materials, and has the same intended uses, transducers and operating modes as the predicate device.



## ***GE Vingmed Ultrasound***

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Section b):

1. **Non-clinical Tests:** The device has been evaluated for acoustic output, biocompatibility, and thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards. Strain Rate Imaging is implemented with Doppler technology which has undergone testing with phantoms and test objects with known characteristics to assure the accuracy of dimensional and dynamic measurements.
2. **Clinical Tests:** None required.

**Conclusion:** Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820 Quality System Regulation and ISO 9001 & 13485 quality system standards. The product is designed to conform with applicable medical device safety standards and compliance is verified through independent evaluation with ongoing production surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Vingmed Ultrasound that the System FiVe / EchoPac with Strain Rate Imaging is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



JUN 11 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

GE VingMed Ultrasound A/S  
C/O Chantel Carson  
Underwriters Laboratories  
333 Pfingsten Road  
Northbrook, IL 60662-2092

RE: K991842  
GE VingMed System FiVe Diagnostic Ultrasound System/  
EchoPac with Strain Rate Imaging  
Dated: May 21, 1999  
Received: May 28, 1999  
Regulatory Class: II  
21 CFR 892.1560, 892.1550 and 892.1570  
Procodes: 90 IYO, 90 IYN and 90 ITX

Dear Mr. Carson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general controls provisions of the Act. 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.

This determination of substantial equivalence also applies to the following transducers intended for use with the VingMed FiVe Diagnostic Ultrasound System as described in your premarket notification:

Transducer Model Number(s):

KG100001/A, KG100001/B, KG100001/C, KK100001/A, KK100001/B, KK100004, KK100005, KN100001, KN100002/B, KN100003, KN100006, KN100007/A, KN100007/B, KN100008, KQ100001, KQ100002, KW100001, TE100024, TG100102, TK100104, TN100047, TN100049, TN1000053, TN100065, TN100119, TQ100001, TQ100002 and TT100101

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic QS inspections, the FDA will verify such assumptions.

Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. *Please note:* this response to your premarket notification does not affect any obligation you may have under sections 531 and 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

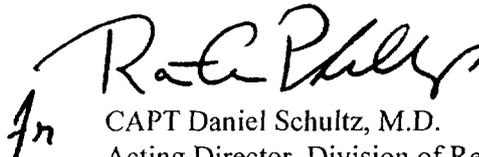
Please be advised that the determination above is based on the fact that no medical devices have been demonstrated to be safe and effective for in vitro fertilization or percutaneous umbilical blood sampling, nor have any devices been marketed for these uses in interstate commerce prior to May 28, 1976, or reclassified into class I (General Controls) or class II (Special Controls). FDA considers devices specifically intended for in vitro fertilization and percutaneous umbilical blood sampling to be investigational, and subject to the provision of the investigational device exemptions (IDE) regulations, 21 CFR, Part 812. Therefore, your product labeling must be consistent with FDA's position on this use.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

If you have any questions regarding the content of this letter, please contact Robert Phillips, Ph.D at (301) 594-1212.

Sincerely yours,



*In* CAPT Daniel Schultz, M.D.  
Acting Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat,  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure(s)

**Attachment A**

**Indications for Use Forms**

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal		P	P	P	P	P	P		P	
Abdominal		P	P	P	P	P	P		P	
Intraoperative (non-neurological)		P	P	P	P	P	P		P	
Intraoperative Neurological										
Pediatric										
Small Organ (breast)		P	P	P		P	P		P	
Neonatal Cephalic		P	P	P	P	P	P		P	
Adult Cephalic		P	P	P	P	P	P		P	
Cardiac		P	P	P	P	P	P		P	
Transesophageal		P	P	P	P	P	P		P	
Transrectal		P	P	P		P	P		P	
Transvaginal		P	P	P		P	P		P	
Transurethral										
Intravascular										
Peripheral Vascular		P	P	P	P	P	P		P	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E  
 Additional Comments: Cardiac is Adult and Pediatric. Small organ includes breast.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD  
 Cardiac includes cardiac analysis applications

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number K991842

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KG 100001/A**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
<b>Abdominal</b>		<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>		<b>P</b>	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
<b>Adult Cephalic</b>		<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>		<b>P</b>	
<b>Cardiac</b>		<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>		<b>P</b>	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number KG11842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KG 100001/B**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
<b>Abdominal</b>		P	P	P	P	P	P		P	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
<b>Adult Cephalic</b>		P	P	P	P	P	P		P	
<b>Cardiac</b>		P	P	P	P	P	P		P	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

*Rita Phelps*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KG 10001/C**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
<b>Abdominal</b>		E	E	E	E	E	E		E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
<b>Adult Cephalic</b>		E	E	E	E	E	E		E	
<b>Cardiac</b>		E	E	E	E	E	E		E	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

*Ruth Puller*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number     K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KK 100001/A**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
<b>Abdominal</b>		P	P	P	P	P	P		P	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
<b>Cardiac</b>		P	P	P	P	P	P		P	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

*Ruth Phelps*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KK 10001/B**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
<b>Abdominal</b>		P	P	P	P	P	P		P	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
<b>Cardiac</b>		P	P	P	P	P	P		P	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

*Rachel Phelps*  
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(Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KK 100004**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
<b>Fetal</b>		P	P	P		P	P		P	
<b>Abdominal</b>		P	P	P		P	P		P	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

*Rachel Phillips*  
 (Division Sign-Off)

Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KK 100005**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
<b>Abdominal</b>		E	E	E	E	E	E		E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
<b>Cardiac</b>		E	E	E	E	E	E		E	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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 Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

*Rae Phillips*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number   K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KN 100001**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
<b>Fetal</b>		P	P	P	P	P	P		P	
<b>Abdominal</b>		P	P	P	P	P	P		P	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
<b>Neonatal Cephalic</b>		P	P	P	P	P	P		P	
Adult Cephalic										
<b>Cardiac</b>		P	P	P	P	P	P		P	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KN 10002/B**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
<b>Abdominal</b>		E	E	E	E	E	E		E	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
<b>Neonatal Cephalic</b>		E	E	E	E	E	E		E	
Adult Cephalic										
<b>Cardiac</b>		E	E	E	E	E	E		E	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices.  
 510(k) Number     K991842    

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KN 100003**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
<b>Peripheral Vascular</b>		<b>P</b>	<b>P</b>	<b>P</b>		<b>P</b>	<b>P</b>		<b>P</b>	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Rachel P. Kelly*

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number

*K991842*

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KN 100006**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
<b>Cardiac</b>		E	E	E	E	E	E		E	
<b>Transesophageal</b>		E	E	E	E	E	E		E	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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*Rate Phelps*  
 \_\_\_\_\_  
 (Division Sign-Off)

Prescription User (Per 21 CFR 801.109)

Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KN 100007/A**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
<b>Cardiac</b>		P	P	P	P	P	P		P	
<b>Transesophageal</b>		P	P	P	P	P	P		P	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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Rita Phelps  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number R991842

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KN 10007/B**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
<b>Cardiac</b>		P	P	P	P	P	P		P	
<b>Transesophageal</b>		P	P	P	P	P	P		P	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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*Rachael Pelly*  
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Prescription User (Per 21 CFR 801.109)

Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number     K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KN 100008**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
<b>Fetal</b>		P	P	P		P	P		P	
<b>Abdominal</b>		P	P	P		P	P		P	
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD

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*Ruth Phelps*  
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 (Division Sign-Off)

Prescription User (Per 21 CFR 801.109)

Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number     K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KQ 100001**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
<b>Transrectal</b>		<b>P</b>	<b>P</b>	<b>P</b>		<b>P</b>	<b>P</b>		<b>P</b>	
<b>Transvaginal</b>		<b>P</b>	<b>P</b>	<b>P</b>		<b>P</b>	<b>P</b>		<b>P</b>	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD

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*Rae Phillips*  
 (Division Sign-Off)  
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 and Radiological Devices  
 510(k) Number K991842

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KQ 100002**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal		E	E	E		E	E		E	
Transvaginal		E	E	E		E	E		E	
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD

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**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe KW 10001**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
<b>Small Organ (breast)</b>		P	P	P		P	P		P	
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
<b>Peripheral Vascular</b>		P	P	P		P	P		P	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Combined modes are B/M, B/Color M, B/PWD, B/Color/PWD

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 510(k) Number R991842

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe TE 100024**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
<b>Cardiac</b>				<b>P</b>	<b>P</b>					
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

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*Rate Phelps*  
 \_\_\_\_\_ Prescription User (Per 21 CFR 801.109)  
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 and Radiological Devices  
 510(k) Number K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe TG 100102**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
<b>Cardiac</b>		P	P	P	P	P	P		P	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

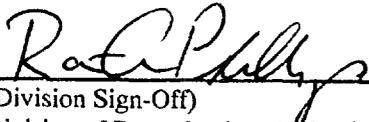
N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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 510(k) Number K991542

Prescription User (Per 21 CFR 801.109)

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe TK 100104**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
<b>Cardiac</b>		P	P	P	P	P	P		P	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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 Division of Reproductive, Abdominal, ENT,  
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Prescription User (Per 21 CFR 801.109)

510(k) Number K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe TN 100047**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
<b>Cardiac</b>		P	P	P	P	P	P		P	
<b>Transesophageal</b>		P	P	P	P	P	P		P	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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*Rate Phillips*  
 \_\_\_\_\_  
 (Division Sign-Off)

Prescription User (Per 21 CFR 801.109)

Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe TN 100049**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal		P	P	P	P	P	P		P	
Intraoperative (non-neurological)		P	P	P	P	P	P		P	
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac		P	P	P	P	P	P		P	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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*Rachel Phillips*  
 \_\_\_\_\_  
 (Division Sign-Off)

Prescription User (Per 21 CFR 801.109)

Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices

510(k) Number K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe TN 100053**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
<b>Cardiac</b>		P	P	P	P	P	P		P	
<b>Transesophageal</b>		P	P	P	P	P	P		P	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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 Division of Reproductive, Abdominal, ENT,  
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510(k) Number K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe TN 100065**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
<b>Transesophageal</b>		<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>		<b>P</b>	
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Roder Phillips*

(Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
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510(k) Number     K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe TN 100119**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
<b>Cardiac</b>		E	E	E	E	E	E		E	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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*Rachael Patel*

(Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
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510(k) Number:     K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe TQ 100001**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
<b>Peripheral Vascular</b>				E	E					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

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*Rosa P...*  
 \_\_\_\_\_  
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510(k) Number K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe TQ 100002**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
<b>Peripheral Vascular</b>				E	E					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

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*R. E. P. [Signature]*

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 Division of Reproductive, Abdominal, ENT,  
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510(k) Number K991842

**Diagnostic Ultrasound Indications for Use Form**

**GE Vingmed System FiVe with Probe TT 100101**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
<b>Cardiac</b>		<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>		<b>P</b>	
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
<b>Peripheral Vascular</b>		<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>	<b>P</b>		<b>P</b>	
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments: Cardiac is Adult and Pediatric.

Combined modes are B/M, B/Color M, B/PWD or CWD, B/Color/PWD or CWD

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

Concurrence of CDRR, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

*Rishi P. [Signature]*  
 (Division Sign-Off)  
 Division of Reproductive, Abdominal, ENT,  
 and Radiological Devices  
 510(k) Number K991842