



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 6, 2016

Philips Ultrasound, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K160807

Trade/Device Name: EPIQ 5 Diagnostic Ultrasound System
EPIQ 7 Diagnostic Ultrasound System
Affiniti 50 Diagnostic Ultrasound System
Affiniti 70 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX

Dated: March 22, 2016

Received: March 24, 2016

Dear Mr. Job:

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. 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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in blue ink that reads "Michael D. O'Hara". The signature is written in a cursive style and is positioned over a faint, large "FDA" watermark.

For

Robert 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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number (if known)

K160807

Device Name

EPIQ 5 Diagnostic Ultrasound System, EPIQ 7 Diagnostic Ultrasound System, Affiniti 50 Diagnostic Ultrasound System, Affiniti 70 Diagnostic Ultrasound System

Indications for Use (Describe)

Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetabl/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal.

The clinical environments where the EPIQ 5, EPIQ 7, Affiniti 50 and Affiniti 70 Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,16,17
	Intra-operative (Cardiac)	P	P	P	P	P	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Intra-operative (Vascular)	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,11,12,13,17
	Adult Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,9,10,11,12,13,17
	Trans-rectal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15,17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
Intra-luminal								
Other: GYN	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15,17	
Other: Urology	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17	
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Other (Fetal Echo)	P	P	P	P	P	Note: 1,2,3,4	Note: 5,6,8,10,12,13,14
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral vascular	P	P	P	P	P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	
Note 9: Color Power Angio (CPA)	
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**
 Transducer: **3D9-3v**
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler**	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,11,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,10,11,12,13, 15
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN		P						
Other: Urology		P	P	P		P		
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication; P= previously cleared (; E= previously cleared by earlier letter to file

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	
Note 9: Color Power Angio (CPA)	
Previous Submission: K043535, HD 11	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: **C5-1**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,16,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN		P	P	P		P	Note: 1,2,3	Note: 5,6,7,8, 9,10,11,12,13, 17
Other: Urology		P	P	P		P	Note: 1,2,3	Note: 5,6,8, 9,10,11,12,13, 17
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6,10,12,13
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: **C8-5**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: **C9-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17	
Other: Urology	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6,10,12,13
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral Vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: **C10-3v**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13, 15, 17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15, 17	
Other: Urology	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15, 17	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,12,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: **C10-4ec**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13,17
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,17
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,17	
Other: Urology	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,17	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,12,13
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral Vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: D2cwc

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult					P		
	Cardiac Pediatric					P		
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: D2tcd

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic			P				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular			P				

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: D5cwc

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel				P			
	Cerebral Vascular				P			

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: L12-3

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
Intra-luminal								
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: L12-5 50

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
Intra-luminal								
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: L15-7io

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Intra-operative (Vascular)	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,8,10,11,12,13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,12,13
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,11,12,13

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: L18-5

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
Intra-luminal								
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: S5-1

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 6,8,9,10,12,13, 17
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 6,8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 6,8,9,10,11,12,13, 17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,9,10,11,12,13, 17
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14, 17
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14, 17
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,13,14
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 6,8,9,10,11,12,13, 17
	Cerebral Vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: S7-3t

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304,EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: S8-3

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 7,8,10,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: ,7,8,10,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,10,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: S12-4

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 8,10,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,10,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 11,12,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**

Transducer: V6-2

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,9,10,11,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**
 Transducer: **VL13-5**
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler**	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,8,10,11,12,13
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6,8,10,11,12,13
	Intra-operative (<i>Cardiac</i>)							
	Intra-operative (<i>Vascular</i>)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 5,6,8,10,11,12,13
	Small Organ (<i>breast, thyroid, testicle</i>)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,10,11,12,13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,10,11,12,13
	Musculo-skel. (Superficial)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,10,11,12,13
Intra-luminal								
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (<i>Fetal Echo</i>)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 5,6,8,10,11,12,13
	Cerebral Vascular	N	N	N		N	Note: 1,2,3	Note: 5,6,8,10,11,12,13

N= new indication; P= previously cleared

Additional Comments:

* New

**Color Doppler includes Color Amplitude Doppler

Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;

Note 2: Combined modes include: B+M+Color

Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD

Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD

Note 5: SonoCT

Note 6: Imaging for guidance of biopsy

Note 7: Infertility monitoring of follicle development

Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging

Note 9: EFOV including Amplitude Doppler

Note 10: Harmonic Imaging

Note 11: Contrast Imaging

Note 12: 3D Imaging

Note 13: XRES

Note 14: TDI

Note 15: Elastography

N= new indication P= previously cleared

Additional Comments:

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 7 Ultrasound System**

Transducer: X5-1

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,9,10,11,12,13
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 7 Ultrasound System**

Transducer: X6-1

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: ,6,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 6,8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: ,6,8,9,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN		P	P	P		P	Note: 1,2,3	Note: ,6,8,9,10,11,12,13
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 6,8,9,10,11,12,13,17
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 6,8,9,10,11,12,13,17

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 7 Ultrasound System**

Transducer: **X7-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler**	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 6,7,8,10,11,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 6,7,8,10,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,13,14
	Cardiac Pediatric	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,13,14
Peripheral Vessel	Peripheral vessel						Note: 1,2,3	
	Cerebral Vascular							

N= new indication; P= previously cleared

Additional Comments:

* New

**Color Doppler includes Color Amplitude Doppler

Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M;

Note 2: Combined modes include: B+M+Color

Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD

Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD

Note 5: SonoCT

Note 6: Imaging for guidance of biopsy

Note 7: Infertility monitoring of follicle development

Note 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging

Note 9: EFOV including Amplitude Doppler

Note 10: Harmonic Imaging

Note 11: Contrast Imaging

Note 12: 3D Imaging

Note 13: XRES

Note 14: TDI

Note 15: Elastography

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
 System: **EPIQ 5 and EPIQ 7 Ultrasound Systems**
 Transducer: X7-2t
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,16,17
	Intra-operative (Cardiac)	N	N	N		N	Note: 1,2,3	Note: 5,8,10,11,12,13
	Intra-operative (Vascular)	N	N	N		N	Note: 1,2,3	Note: 5,8,10,11,12,13
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Neonatal Cephalic	N	N	N		N	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Adult Cephalic	N	N	N		N	Note: 1,2,3	Note: 8,10,11,12,13
	Trans-rectal	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Trans-vaginal	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15,17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Musculo-skel. (Superficial)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
Intra-luminal								
Other: GYN	N	N	N		N		Note: 5,6,7,8,9,10,11,12,13,15,17	
Other: Urology	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17	
Cardiac	Cardiac Adult	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Trans-esophageal (Cardiac)	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Other (Fetal Echo)	N	N	N	N	N	Note: 1,2,3,4	Note: 5,6,8,10,12,13,14
Peripheral Vessel	Peripheral vessel	N	N	N	N	N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral Vascular	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note:17 PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Ultrasound System**

Transducer: **C5-1**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,9,10,11,12,13,15,16,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN		P	P	P		P	Note: 1,2,3
Other: Urology		P	P	P		P	Note: 1,2,3	Note: 5,6,8, 9,10,11,12,13,17
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6,10,12,13
Peripheral Vessel	Peripheral Vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note:17 PercuNav
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **C6-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6, 8,9,10,11,12,13,15
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN		N	N	N		N	Note: 1,2,3
Other: Urology		N	N	N		N	Note: 1,2,3	Note: 5,6,8, 9,10,11,12,13
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	N	N	N		N	Note: 1,2,3	Note: 5,6,10,12,13
Peripheral Vessel	Peripheral Vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **C8-5**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,9,,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,11,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,11,12,13

E = added via Appendix E

N= new indication

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Ultrasound System**

Transducer: **C9-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17	
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6,10,12,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared (K132304)

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note:17 PercuNav
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Ultrasound System**

Transducer: **C10-3v**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6,7, 8,10,11,12,13, 15
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15	
Other: Urology	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,12,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **3D9-3v**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6,7, 8,10,11,12,13
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13	
Other: Urology	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,12,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K043535, HD 11	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **C9-4v**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6,7, 8,10,11,12,13, 15
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN		P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15
Other: Urology		N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,10,12,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K120321, ClearVue 350/550	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **C10-4ec**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)							
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13,17	
	Abdominal								
	Intra-operative (Cardiac)								
	Intra-operative (Vascular)								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testicle)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal		P	P	P		P	Note: 1,2,3	Note: 5,6,7, 8,9,10,11,12,13,17
	Trans-vaginal		P	P	P		P	Note: 1,2,3	Note: 5,6,7, 8,9,10,11,12,13,17
	Trans-urethral								
	Trans-esoph. (non-Cardiac)								
	Musculo-skel. (Conventional)								
	Musculo-skel. (Superficial)								
	Intra-luminal								
Other: GYN									
Other: Urology		P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,17	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esophageal (Cardiac)								
	Other (Fetal Echo)		P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,11,12,13
Peripheral Vessel	Peripheral Vessel								
	Cerebral Vascular								

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note:17 PercuNav
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **BP10-5ec**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)							
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)	
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal / OB								
	Abdominal								
	Intra-operative (Cardiac)								
	Intra-operative (Vascular)								
	Laparoscopic								
	Pediatric								
	Small Organ (breast, thyroid, testicle)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal		P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Cardiac)								
	Musculo-skel. (Conventional)								
	Musculo-skel. (Superficial)								
	Intra-luminal								
	Other: GYN								
Other: Urology		N	N	N		N		Note: 5,6,8,9,10,11,12,13	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Trans-esophageal (Cardiac)								
	Other (Fetal Echo)								
Peripheral Vessel	Peripheral vessel								
	Cerebral Vascular								

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K081661, HD 15	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **D2cwc**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **D2tcd**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic			P				
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **D5cwc**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel				P			
	Cerebral Vascular				P			

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Ultrasound System**

Transducer: **L12-3**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **L12-4**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6, 8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Cerebral Vascular	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K120321, ClearVue 350/550	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **L12-5 50**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note:17 PercuNav
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **L15-7io**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6, 8,9,10,11,12,13
	Intra-operative (Cardiac)	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Intra-operative (Vascular)	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,11,12,13
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

E = added via appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **L18-5**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,11,12,13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

E = added via Appendix E

N= new indication

P= previously cleared (K132304)

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Ultrasound System**

Transducer: **S5-1**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,9,10,11,12,13,17
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note:17 PercuNav
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **S4-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6, 8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,9,10,11,12,13
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	2.0 Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	3.0 Note 15: Elastography
Note 7: Infertility monitoring of follicle development	4.0 Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	5.0
Previous submission: K043535, HD11	6.0

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **S7-3t**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **S8-3**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 7,8,9,10,12,13
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 8,10,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,10,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Ultrasound System**

Transducer: **S12-4**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,9,10,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **V6-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,9,10,11,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared (K132304)

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **X7-2t**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult	N	N	N	N	N	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 and Affiniti 50 Ultrasound Systems**

Transducer: **VL13-5**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13
	Cerebral Vascular	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging (for LVO applications)
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic imaging	

510(k) Summary of Safety and Effectiveness

EPIQ 5, EPIQ 7, Affiniti 50 and Affiniti 70 Diagnostic Ultrasound Systems

This summary of safety and effectiveness information is submitted in accordance with 21CFR §807.92

1. Submitter’s name, address, telephone number, contact person.

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Date prepared: March 21, 2016

2. Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known:

Common/usual name: Diagnostic ultrasound system and transducers
 Proprietary name: EPIQ 7 Diagnostic Ultrasound System
 EPIQ 5 Diagnostic Ultrasound System
 Affiniti 50 Diagnostic Ultrasound System
 Affiniti 70 Diagnostic Ultrasound System

Within this notification,

- the reference to EPIQ represents both the EPIQ 7 and the EPIQ 5,
- the reference to Affiniti represents both the Affiniti 70 and the Affiniti 50.

These devices are classified as follows:

Classification Name	21 CFR Section	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	IYN
Ultrasonic Pulsed Echo Imaging System	892.1560	IYO
Diagnostic Ultrasound Transducer	892.1570	ITX

As stated in 21 CFR, parts 892.1550, 892.1560, and 892.1570, each of these generic types of devices has been classified as Class II.

3. Substantially Equivalent Devices

Philips Ultrasound believes the proposed EPIQ and Affiniti Ultrasound Systems are substantially equivalent to the following currently marketed devices:

Product	510(k)
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Below is a comparison to the predicate devices:

Standard Feature	EPIQ K132304 (Predicate Device)	EPIQ 1.5 (Proposed Device)	Affiniti 1.5 (Proposed Device)
Indication for Use	Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal	Same	Same
Transducers	<ul style="list-style-type: none"> • C5-1 • C8-5 • C9-2 • C10-3v • C10-4ec • D2cwc • D5cwc • L12-3 • L12-5 50 • L15-7io • L18-5 • S5-1 • S7-3t • S8-3 • S12-4 • V6-2 • X7-2t • D2tcd • X5-1 • X6-1 	<p>Same with the following additional transducers with no new indications</p> <ul style="list-style-type: none"> • VL13-5 • X7-2 • 3D9-3v <p>The new transducers introduce neither new indications for use nor new patient contact material.</p>	<p>Same with the following additional transducers with no new indications</p> <ul style="list-style-type: none"> • S4-2 • 3D9-3v • C9-4v • C6-2 • BP10-5ec • L12-4 • VL13-5 <p>The new transducers introduce neither new indications for use nor new patient contact material.</p> <p>Affiniti does not include:</p> <ul style="list-style-type: none"> • X5-1 • X6-1
Transducer	<ul style="list-style-type: none"> • Phased array 	Same	Same *

Standard Feature	EPIQ K132304 (Predicate Device)	EPIQ 1.5 (Proposed Device)	Affiniti 1.5 (Proposed Device)
Types	<ul style="list-style-type: none"> • Linear array • Curved array • Pencil Probes • Multi-plane Transesophageal • Motorized arrays • 3D Matrix Array 		*Affiniti does not have 3D Matrix Array transducers
Transducer Frequency	1.0 – 18.0 MHz	Same	Same
Acoustic Output Display & FDA Limits	IEC 62359 <ul style="list-style-type: none"> • ISPTA max=720 mw/cm2 • MI max =1.9 • MI display • TI display 	Same	Same
Imaging Mode	<ul style="list-style-type: none"> • 2D Echo Imaging • M-mode Echo Imaging • PW Doppler Imaging • CW Doppler Imaging • 2D Color Doppler Imaging • Color Power Angio (CPA) • Color Amplitude Doppler • M Mode Color Doppler Imaging • Broadband Imaging • Harmonic Imaging • 2D Tissue Doppler (TDI) • Combination modes 	Same	Same
# Transmit Channels	128	Same	Same
# Receive Channels	256	Same	Same
510(k) Track	Track 3	Same	Same
System Characteristics	<ul style="list-style-type: none"> • Beamformer 128/128 • Mobile cart • Single LCD monitor 	Same	Same* *The Affiniti cart is smaller. Brakes are locking casters on Affiniti while EPIQ has integrated brakes and a control pedal.
Product Safety Certification	CSA International	Same	Same

Standard Feature	EPIQ K132304 (Predicate Device)	EPIQ 1.5 (Proposed Device)	Affiniti 1.5 (Proposed Device)
EMC Compliance	C22.2 No. 60601-1 IEC 60601-1 IEC 60601-1-2 ANSI/AAMI ES60601-1 IEC 60601-2-37	Same	Same
Patient Contact Materials	All patient contact materials of the EPIQ Ultrasound System and transducers are detailed in K132304.	Same No new patient contact materials comparing with the predicates.	Same No new patient contact materials comparing with the predicates.
Accessories	<ul style="list-style-type: none"> • Various hardcopy, recording and printing devices: video thermal printer, report printer, DVD, USB • PercuNav Instruments • Biopsy guides • Footswitch 	Same	Same

4. Device Description

The proposed EPIQ and Affiniti Diagnostic Ultrasound Systems, which includes EPIQ 5, EPIQ 7, Affiniti 50 and Affiniti 70 systems, are general purpose, software controlled, diagnostic ultrasound systems. Their function is to acquire ultrasound data and to display the data in various modes of operation.

The devices consist of two parts: the system console and the transducers. The system console contains the user interface, a display, system electronics and optional peripherals (ECG, printers). In addition to the physical knobs and buttons of the main control panel, the user interface consists of a touch screen with soft key controls. EPIQ also has a QWERTY keyboard.

The removable transducers are connected to the system using a standard technology, multi-pin connectors. The proposed EPIQ and Affiniti systems use standard transducer technology, and supports phased, linear, curved linear array, TEE, motorized 3D curved linear arrays as well as non-imaging (pencil) probes.

Clinical data storage consists of a local repository as well as off-line image storage via the network, DVR, DVD, and USB storage devices. The images are stored in industry-standard formats (e.g. JPEG, AVI, DICOM) and are intended to be readable using industry-standard hardware and software. On-line review of the images is available. Secure access tools are provided to restrict and log access to the clinical data repository according to HIPAA.

The system circuitry generates an electronic voltage pulse, which is transmitted to the transducer. In the transducer, a piezo electric array converts the electronic pulse into an

ultrasonic pressure wave. When coupled to the body, the pressure wave transmits through body tissues. The Doppler functions of the system process the Doppler shift frequencies from the echoes of moving targets such as blood to detect and graphically display the Doppler shifts of these tissues as flow.

The proposed EPIQ and Affiniti systems give the operator the ability to measure anatomical structures and offer analysis packages that provide information used by competent healthcare professionals to make a diagnosis. The proposed EPIQ and Affiniti systems enable image guided navigation and image fusion via the optional PercuNav feature (K121498).

5. Technological Comparison to Predicate Devices

The proposed EPIQ and Affiniti ultrasound systems, and the predicate device EPIQ ultrasound system cleared in K132304 are track 3 systems and employ the same fundamental scientific technology. They are the same in indications for use, materials, type of transducers, optimization, accessories and imaging modes. The primary differences between the proposed EPIQ and Affiniti systems and the predicate device EPIQ system are as follows:

- Integration of QLAB Heart Model software which was cleared via K130159 and K132165.
- Addition of the new security features to help the healthcare providers be compliant with HIPAA and the regulations imposed by the other governmental and regulatory bodies.
- Integration of a service tool called OmniSphere. OmniSphere gives the Ultrasound system the ability to create utilization reports which describe how the system is being used. OmniSphere also allows the Biomedical Engineer within a medical facility to remotely log into a connected system to perform service related operations.
- Update of the analysis packages to allow the acquisition and export of measurements and calculations in the fetal echo DICOM template and the small parts DICOM template, to allow the standardization of user defined measurement export, and to include new or newly standardized measurements from standards bodies e.g. ASE, AIUM, ACEP.
- Addition of the following transducers: VL13-5, X7-2, 3D9-3v, S4-2, C9-4v, C6-2, BP10-5ec, L12-4.

6. Indications for Use

Abdominal, Cardiac Adult, Cardiac other (Fetal), Cardiac Pediatric, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal.

The clinical environments where the EPIQ and Affiniti Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients.

7. Safety Considerations

As track 3 ultrasound devices the proposed EPIQ and Affiniti Ultrasound Systems are designed to comply with the acoustic output display requirements of IEC 60601-2-37 Ed 2.0 (Particular requirements for the basic safety and essential performance of ultrasonic medical and monitoring equipment) and IEC 62359, Ed 2.0 (Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields).

The proposed EPIQ and Affiniti Ultrasound Systems comply with the referenced standard as well as the FDA ultrasound specific guidance, Guidance for Industry and FDA Staff – Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers (September 9, 2008).

The system acoustic output limits are:

- $Ispta.3 \leq 720 \text{ MW/cm}^2$
- $MI \leq 1.9$
- $TI \leq 6.0$

The system and transducers are compliant to:

- IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2007
- IEC 60601-1-6 Medical Electrical Equipment – Part 1-6, General Requirements for Basic Safety and Essential Performance – Usability, 2010
- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2007
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2010

8. Nonclinical Performance Data

Philips Ultrasound performed the following testing to ensure the safety and effectiveness of the proposed EPIQ and Affiniti systems:

- Software Verification and Validation
- Non-Clinical Performance Data
- Non-Clinical Tests
 - IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
 - IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2007
 - IEC 60601-1-6 Medical Electrical Equipment – Part 1-6, General Requirements for Basic Safety and Essential Performance – Usability, 2010

- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2007
- ISO 10993: Biological evaluation of medical devices.
- Quality assurance measures applied to the system design and development include, but were not limited to:
 - Risk Analysis
 - Product Specifications
 - Design Reviews
 - Verification and Validation

9. Clinical Data

Clinical data was not required to demonstrate safety and effectiveness of the proposed EPIQ and Affiniti Diagnostic Ultrasound Systems since the proposed EPIQ or Affiniti system introduces no new indications for use, modes or features that have not been previously cleared with the predicate device EPIQ system (K132304). The clinical safety and effectiveness of ultrasound systems with these characteristics are well accepted for both predicate and subject devices.

10. Conclusion

The proposed EPIQ and Affiniti Ultrasound Systems are substantially equivalent in safety and effectiveness to the predicate device identified above:

- The predicate device and the proposed EPIQ and Affiniti systems are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- The predicate device and the proposed EPIQ and Affiniti systems have the same gray-scale and Doppler capabilities.
- The predicate device and the proposed EPIQ and Affiniti systems use essentially the same technologies for imaging, Doppler functions and signal processing.
- The predicate device and the proposed EPIQ and Affiniti systems have acoustic output levels within the Track 3 FDA limits.
- The predicate device and the proposed EPIQ and Affiniti systems are manufactured under equivalent quality systems.
- The predicate device and the proposed EPIQ and Affiniti systems are manufactured of materials with equivalent bio safety. There is no new material or material change in application.
- The predicate device and the proposed EPIQ and Affiniti systems are designed and manufactured to the same electrical and physical safety standards.

514 Performance Standards

There are no Sec. 514 performance standards for the proposed EPIQ and Affiniti systems.

Prescription Status

The proposed EPIQ and Affiniti systems are prescription devices. The prescription device statement appears in the labeling.

Sterilization Sites

Not applicable. No components are supplied sterile.

Track

The proposed EPIQ and Affiniti systems are Track 3 systems