



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Philips Ultrasound, Inc.
% Ms. Peng Cui
Senior Regulatory Specialist
3000 Minuteman Road
ANDOVER MA 01810

January 10, 2017

Re: K163120

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: November 8, 2016

Received: November 9, 2016

Dear Ms. Cui:

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 over a large, semi-transparent watermark of the FDA logo.

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

Indications for Use

510(k) Number (if known)

K163120

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.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Diagnostic 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: 5,6,8,9,10,11,12,13,15,16,17,18
	Intra-operative (Cardiac)	P	P	P	P	P	Note: 1,2,3	Note: 5,8,9,10, 12,13
	Intra-operative (Vascular)	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10, 12,13
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 12,13,17,18
	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: 5,8,9,10,12,13,17
	Adult Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,9,10, 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, ,12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, ,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, ,12,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10, ,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 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	
Previous submission: K132304, K160807, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Diagnostic 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,,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,,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,,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 Diagnostic 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: 5,6,8,9,10,11,12,13,16,17,18
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13,17,18
	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, 9,10,12,13,17
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
	Note 18: ElastQ Imaging
Previous submission: K132304, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Diagnostic 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,,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,,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,,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13

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 Diagnostic 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, ,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, 12,13
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 12,13, 17	
Other: Urology	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, ,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 Diagnostic 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: 5,6,7,8,9,10,12,13,15, 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 Diagnostic 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, 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, 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, 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 Diagnostic 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 Diagnostic 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 Diagnostic 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 Diagnostic 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, 12,13, 17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)	N	N	N		N		
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 12,13, 17
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 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, ,12,13, 17
Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 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 Diagnostic 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, 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, 12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 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, 12,13,17
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 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 Diagnostic 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,,12,13
	Intra-operative (Vascular)	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,,12,13
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,8,10,,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,,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,,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 Diagnostic 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,,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,,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,,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13,15,17
	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,,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,,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,,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 Diagnostic 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, 12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 6,8,9,10, 12,13, 17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,9,10, , 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, 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, 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 Diagnostic 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	P	P	P	P	P	Note: 1,2,3,4	Note: 10,,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,,12,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,,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 Diagnostic 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,,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,,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,,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 Diagnostic 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,,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: ,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: ,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 Diagnostic 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,,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,,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,,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 Diagnostic 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 r**	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,,12,13
	Intra-operative (<i>Cardiac</i>)							
	Intra-operative (<i>Vascular</i>)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,,12,13
	Small Organ (<i>breast, thyroid, testicle</i>)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,,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: 5,6,8,10,,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,,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	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,,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

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
 System: **EPIQ 7 Diagnostic Ultrasound Systems**
 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, ,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 8,9,10, 12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,9,10, 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, 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 Diagnostic Ultrasound Systems**
 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, 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, 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, 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 Diagnostic Ultrasound Systems**

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	P	P	P		P	Note: 1,2,3	Note: 6,7,8,10,,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 6,7,8,10,,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	P	P	P	P	P	Note: 1,2,3,4	Note: 10,,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,,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 Diagnostic 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,,12,13,14
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,,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 7 Diagnostic Ultrasound Systems**
 Transducer: X8-2t
 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: 10,12,13,14
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	N	N	N	N	N	Note: 1,2,3,4	Note: 10,12,13,14
	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: K123754 CX50 System	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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: 1,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,15,16,17
	Intra-operative (Cardiac)	P	P	P		P	Note: 1,3	Note: 5,8,10,12,13
	Intra-operative (Vascular)	P	P	P		P	Note: 1,3	Note: 5,8,10,12,13
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,15,17
	Neonatal Cephalic	P	P	P		P	Note: 1,3	Note: 5,8,9,10,12,13
	Adult Cephalic	P	P	P		P	Note: 1,3	Note: 8,10,12,13
	Trans-rectal	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	Trans-vaginal	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13,15,17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	Intra-luminal							
Other: GYN	P	P	P		P		Note: 5,6,7,8,9,10,11,12,13,15,17	
Other: Urology	P	P	P		P	Note: 1,3	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: 10,12,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,12,13,14
	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: 1,3	Note: 5,6,8,9,10,12,13,17
	Cerebral Vascular	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17

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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Diagnostic 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: 1,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal	P	P	P		P	Note: 1,3	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: 1,3	Note: 5,6,8,9,10,12,13,17
	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: 1,3	Note: 5,6,7,8,9,10,12,13,17
Other: Urology		P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,3	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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,3	Note: 5,6, 8,9,10,11,12,13,15
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	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		P	P	P		P	Note: 1,3	Note: 5,6,7,8, 9,10,12,13
Other: Urology		P	P	P		P	Note: 1,3	Note: 5,6,8, 9,10,12,13
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,3	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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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: 1,3	Note: 5,6,8,9,,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	P	P	P		P	Note: 1,3	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: 1,3	Note: 5,6,8,9,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,3	Note: 5,6,8,9,12,13

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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Diagnostic 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: 1,3	Note: 5,6,8,9,10,12,13,17
	Abdominal	P	P	P		P	Note: 1,3	Note: 5,6, 8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	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: 1,3	Note: 5,6,8,9,10,12,13,17
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17	
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,3	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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Diagnostic 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: 1,3	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: 1,3	Note: 5,6,7, 8,10,12,13, 15
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN		P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,11,12,13,15
Other: Urology		P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13,15
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,3	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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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: 1,3	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: 1,3	Note: 5,6,7, 8,10,12,13
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13	
Other: Urology	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,3	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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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: 1,3	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: 1,3	Note: 5,6,7, 8,10,12,13, 15
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,11,12,13,15	
Other: Urology	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13,15	
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,3	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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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: 1,3	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: 1,3	Note: 5,6,7, 8,9,10,12,13,17
	Trans-vaginal	P	P	P		P	Note: 1,3	Note: 5,6,7, 8,9,10,12,13,17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN								
Other: Urology	P	P	P		P	Note: 1,3	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: 1,3	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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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: 1,3	Note: 5,6,8,9,10,12,13
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN								
Other: Urology	P	P	P		P		Note: 5,6,8,9,10,12,13	
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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Diagnostic 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	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,3	Note: 5,6, 8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13
	Neonatal Cephalic	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,3	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: 1,3	Note: 5,6,8,9,10,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13

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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,3	Note: 5,6, 8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13
	Neonatal Cephalic	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,3	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: 1,3	Note: 5,6,8,9,10,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13

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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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: 1,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal	P	P	P		P	Note: 1,3	Note: 5,6, 8,9,10,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,3	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: 1,3	Note: 5,6,8,9,10,12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
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: 1,3	Note: 5,6,8,9,10,12,13,17
	Cerebral Vascular	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17

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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **L15-7i0**

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: 1,3	Note: 5,6, 8,9,10,12,13
	Intra-operative (Cardiac)	P	P	P		P	Note: 1,3	Note: 5,8,9,10,12,13
	Intra-operative (Vascular)	P	P	P		P	Note: 1,3	Note: 5,8,9,10,12,13
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,3	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: 1,3	Note: 5,6,8,9,10,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13

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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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: 1,3	Note: 5,6, 8,9,10,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,3	Note: 5,6,8,10,12,13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,3	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: 1,3	Note: 5,6,8,9,10,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13

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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Diagnostic 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							
	Abdominal	P	P	P		P	Note: 1,3	Note: 5,6, 8,9,10,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P		P	Note: 1,3	Note: 8,9,10,12,13,17
	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: 10,12,13,14
	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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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: 1,3	Note: 5,6, 8,9,10,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P		P	Note: 1,3	Note: 8,9,10,12,13
	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: 10,12,13,14
	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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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	P	P	P	P	P	Note: 1,2,3,4	Note: 10,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,12,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,12,13,14
	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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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: 1,3	Note: 7,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,3	Note: 8,9,10,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 8,10,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	P	P	P		P	Note: 1,3	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: 10,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,12,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P	P	P	Note: 1,3	Note: 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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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	P	P	P		P	Note: 1,3	Note: 8,9,10,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 8,9,10,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	P	P	P		P	Note: 1,3	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: 10,12,13,14
	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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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: 1,3	Note: 5,6,8,9,10,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	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: 1,3	Note: 5,9,10,13
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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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	E	E	E	E	E	Note: 1,2,3,4	Note: 10,12,13,14
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,12,13,14
	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
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: K160807, Affiniti system	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic 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)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	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	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13

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
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: K160807, Affiniti system	

510(k) Summary of Safety and Effectiveness

EPIQ and Affiniti 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.

Philips Ultrasound, Inc.
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Bothell, WA 98021-8431

Contact person: Peng Cui, Regulatory Affairs Specialist
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Date prepared: November 7, 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 5 Diagnostic Ultrasound System
EPIQ 7 Diagnostic Ultrasound System
Affiniti 50 Diagnostic Ultrasound System
Affiniti 70 Diagnostic Ultrasound System

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 Diagnostic Ultrasound Systems** are substantially equivalent to the following currently marketed devices:

Product		510(k)
Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic	Primary Predicate Device	K160807

Ultrasound System		
SuperSonic AIXPLORER with ShearWave™ Elastography	Predicate Device	K112255, K142100

4. Device Description

The proposed **EPIQ and Affiniti Diagnostic Ultrasound 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). The removable transducers are connected to the system using a standard technology, multi-pin connectors.

5. 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 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.

6. Technological Comparison to Predicate Devices

The **proposed EPIQ and Affiniti Diagnostic Ultrasound Systems** and the currently marketed and predicate device, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System (K160807), employ the same fundamental scientific technology. The primary difference is the addition of the ElastQ Imaging and the new transducer X8-2t to the EPIQ system. The ElastQ Imaging is a quantitative elastography technique for tissue stiffness measurement. Note that the ElastQ imaging utilizes the same fundamental scientific technology as provided with the predicate device, SuperSonic AIXPLORER with ShearWave™ Elastography (K112255, K142100). The X8-2t transducer is a derivative of the cleared and marketed X7-2t cleared for use with the currently marketed and predicate device, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System transducer (K160807). The new transducer X8-2t is made from the same material and is provided with an additional button installed on the handle, for ease of use. Its frame rate has been increased to improve imaging quality and workflow has been improved. The new X8-2t transducer does not introduce new indications for use.

A comparison of the proposed **EPIQ and Affiniti Diagnostic Ultrasound Systems** to the currently marketed and predicate device, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System, and SuperSonic AIXPLORER with ShearWave™ Elastography is provided in Table 1 below:

Table 1					
Comparison of the proposed EPIQ and Affiniti Diagnostic Ultrasound Systems to the currently marketed and predicate device, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System, and and SuperSonic AIXPLORER with ShearWave™ Elastography					
Standard Feature	SuperSonic AIXPLORER with ShearWave™ Elastography, K112255, K142100 (Predicate device)	EPIQ K160807, K132304 (Primary Predicate Device)	EPIQ 1.7 (Proposed Device)	Affiniti 1.7 K160807 (Primary Predicate Device)	Affiniti 1.7 (Proposed Device)
Indications for Use	Abdominal, Small organs, Musculoskeletal, Superficial Musculoskeletal, Vascular, Peripheral Vascular, Intraoperative, OB-GYN, Pelvic, Pediatric, Urology, Trans-rectal, Trans-vaginal and Neonatal/adult Cephalic.	Fetal/Obstetric, Abdominal, Intraoperative (Vascular), Intraoperative (Cardiac), Pediatric, Small Organ (Breast, Thyroid, Testicle), Cephalic (Neonatal), Cephalic (Adult), Transrectal, Transvaginal Musculoskeletal (Conventional), Musculoskeletal (Superficial) Gynecological, Other: Urology, Cardiac Adult, Cardiac Pediatric, Transesophageal (Cardiac), Cardiac other (Fetal), Peripheral Vessel, Cerebral Vascular,	Same as EPIQ K160807	Same as EPIQ K160807	Same as EPIQ K160807
Transducers		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, VL13-5,X7-2 , 3D9-3v	Same as EPIQ K160807 with addition of X8-2t	3D9-3v, C5-1, C6-2, C8-5,C9-2, C9-4V, C10-3v, C10-4ec, D2cwc, D2tcd, D5cwc, BP10-5ec, L12-3, L12-4,L12-5, L15-7io, L18-5, S4-2, S5-1, S7-3t, S8-3, S12-4, V6-2, VL13-5, X7-2t	Same as Affiniti K160807
Transducer Types		<ul style="list-style-type: none"> • Phased array • Linear array • Curved array • Pencil Probes • Multi-plane Transesophageal • Motorized arrays • 3D Matrix Array 	Same as EPIQ K160807	<ul style="list-style-type: none"> • Phased array • Linear array • Curved array • Pencil Probes • Multi-plane Transesophageal • Motorized arrays 	Same as Affiniti K160807

Table 1

Comparison of the proposed **EPIQ and Affiniti Diagnostic Ultrasound Systems** to the currently marketed and predicate device, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System, and and SuperSonic AIXPLORER with ShearWave™ Elastography

Standard Feature	SuperSonic AIXPLORER with ShearWave™ Elastography, K112255, K142100 (Predicate device)	EPIQ K160807, K132304 (Primary Predicate Device)	EPIQ 1.7 (Proposed Device)	Affiniti 1.7 K160807 (Primary Predicate Device)	Affiniti 1.7 (Proposed Device)
Transducer Frequency		1.0 – 18.0 MHz	Same	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	Same
Imaging Mode	B mode, M mode, PWD, Color Doppler, Combined modes,	B mode, M mode, PWD, CWD, Color Doppler, Combined modes,	Same	Same	Same
Shear wave Elastography		ElastPQ	Same	Same	Same
	ShearWave™ Elastography	NA	ElastQ Imaging *ElastQ imaging is similar to ShearWave™ Elastography (K112255, K142100)	NA	NA
# Transmit Channels		128	Same	Same	Same
# Receive Channels		256	Same	Same	Same
510(k) Track		Track 3	Same	Same	Same
Product Safety Certification		CSA International	Same	Same	Same
EMC Compliance		C22.2 No. 60601-1 IEC 60601-1 IEC 60601-1-2 ANSI/AAMI ES60601-1 IEC 60601-2-37	Same	Same	Same
Patient Contact Materials		No changes from EPIQ K160807			
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	Same

7. Safety Considerations

As a Track 3 ultrasound device, the subject **EPIQ and Affiniti Diagnostic 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 subject **EPIQ and Affiniti Diagnostic Ultrasound Systems** comply with the referenced standard as well as the FDA ultrasound guidance document, Guidance for Industry and FDA Staff – Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, issued on 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 Diagnostic Ultrasound Systems**:

:

- ElastQ Imaging Acoustic Output Test – The purpose of this testing is to understand the thermal implications of the ElastQ Imaging
- ElastQ Imaging Measurement Report – A bench test of the EPIQ Diagnostic Ultrasound System in ElastQ Imaging mode in order to verify precision.

- X8-2t Transducer Verification Report - To confirm X8-2t meets its specifications.
- Software Verification and Validation – Standard verification and validation testing in order to ensure the system meets specifications and use needs.
- 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

The **proposed EPIQ and Affiniti Diagnostic Ultrasound Systems** did not require clinical study, since substantial equivalence to the currently marketed predicate devices, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System and SuperSonic AIXPLORER with ShearWave™ Elastography, respectively, was demonstrated with the following attributes:

- Design features;
- Indication for use;
- Fundamental scientific technology;
- Non-clinical performance testing; and
- Safety and effectiveness.

10. Conclusion

The **proposed EPIQ and Affiniti Diagnostic Ultrasound Systems** with the ElastQ Imaging and the new transducer X8-2t are substantially equivalent with regards to safety and effectiveness to the currently marketed predicate device, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System and SuperSonic AIXPLORER with ShearWave™ Elastography, as follows :

- The predicate device and the proposed **EPIQ and Affiniti Diagnostic Ultrasound Systems** are indicated for the diagnostic ultrasonic imaging and fluid flow analysis.

- The predicate device and the proposed **EPIQ and Affiniti Diagnostic Ultrasound Systems** have the same gray-scale and Doppler capabilities.
- The predicate device and the proposed **EPIQ and Affiniti Diagnostic Ultrasound Systems** use essentially the same technologies for imaging, Doppler functions and signal processing.
- The predicate device and the proposed **EPIQ and Affiniti Diagnostic Ultrasound Systems** have acoustic output levels within the Track 3 FDA limits.
- The predicate device and the proposed **EPIQ and Affiniti Diagnostic Ultrasound Systems** are manufactured under equivalent quality systems.
- The predicate device and the proposed **EPIQ and Affiniti Diagnostic Ultrasound 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 Diagnostic Ultrasound 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 Diagnostic Ultrasound Systems**.

Prescription Status

The proposed **EPIQ and Affiniti Diagnostic Ultrasound 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 Diagnostic Ultrasound Systems** are Track 3 systems.

