



July 27, 2018

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

Re: K181485

Trade/Device Name: EPIQ , EPIQ 5, EPIQ 7, Affiniti 30, Affiniti 50 and 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: July 17, 2018

Received: July 18, 2018

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

A handwritten signature in black ink, appearing to read "ROBERT A. OCHS", is written over a large, light blue, semi-transparent watermark of the letters "FDA". The signature is followed by the word "for" in a standard black font.

Robert A. Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K181485

Device Name

EPIQ 5 Diagnostic Ultrasound System, EPIQ 7 Diagnostic Ultrasound System, EPIQ Diagnostic Ultrasound System, Affiniti 30 Diagnostic Ultrasound System, Affiniti 50 Diagnostic Ultrasound System, Affiniti 70 Diagnostic Ultrasound System

Indications for Use (Describe)

The intended use of the EPIQ, EPIQ 5, EPIQ 7, Affiniti 30, Affiniti 50 and Affiniti 70 Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following Indications for Use: Abdominal, Cardiac Adult, Cardiac other (Fetal), Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Intraoperative (Cardiac), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Other: Urology, Pediatric, Peripheral Vessel, Small Organ (Breast, Thyroid, Testicle), Transesophageal (Cardiac), Transrectal, Transvaginal.

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

When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live Echo Guidance.

The systems are intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information, and only for the purposes for which it was designed. However, nothing stated in the user information reduces your responsibility for sound clinical judgement and best clinical procedure.

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

Prescription Use (Part 21 CFR 801 Subpart D)

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,16,17,18,19
	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: 5,6,8,9,10,11,12,13,15,17,19
	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)	Note 19: ElastQ Imaging Linear
Previous submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **3D9-3v**

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

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

N= new indication; P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	
Note 9: Color Power Angio (CPA)	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **C5-1**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,16,17,18
	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: 5,6,8,9,10,11,12,13,17
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6,10,12,13
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **C8-5**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13
	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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **C9-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13, 17
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13, 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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **C10-3v**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13, 15, 17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15, 17	
Other: Urology	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,,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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **EPIQ, EPIQ 7, and EPIQ 5 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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: D2cwc

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: D2tcd

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: D5cwc

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: L12-3

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13, 17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)	P	P	P		P		
	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: 5,6,8,9,10,11,12,13, 17
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13, 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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: L12-5 50

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,12,13, 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: 5,6,8,9,10,11,12,13

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: K172607, EPIQ/Affiniti	

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

Transducer: eL18-4

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: 1,2,3	Note: 5,6,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17,19
	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, 18,19
	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: 5,6,8,9,10,11,12,13,17
	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 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)	Note 19: ElastQ Imaging Linear
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: L15-7io

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,12,13
	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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: L18-5

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13
	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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: S5-1

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 6,8,9,10,12,13, 17
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 6,8,9,10,12,13,17
	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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: S7-3t

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult	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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: S8-3

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 7,8,10,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: ,7,8,10,12,13
	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: K172607, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: S9-2

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 7,8,10,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: ,7,8,10,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	N	N	N		N	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	N	N	N	N	N	Note: 1,2,3,4	Note: 10,12,13,14
	Cardiac Pediatric	N	N	N	N	N	Note: 1,2,3,4	Note: 10,12,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	N	N	N	N	N	Note: 1,2,3,4	Note: 10,12,13,14
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:	

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

Transducer: S12-4

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 8,10,12,13
	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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: V6-2

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13
	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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **VL13-5**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	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:

*Color Doppler includes Color Amplitude Doppler	Note 9: EFOV including Amplitude Doppler
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 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 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: X5-1

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 8,9,10,12,13
	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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: X6-1

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: ,6,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 6,8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: ,6,8,9,10,12,13,17
	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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **X7-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 6,7,8,10,11,12,13
	Abdominal							
	Intra-operative (<i>Cardiac</i>)							
	Intra-operative (<i>Vascular</i>)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 6,7,8,10,12,13
	Small Organ (<i>breast, thyroid, testicle</i>)							
	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 (<i>Fetal Echo</i>)	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:

*Color Doppler includes Color Amplitude Doppler	Note 9: EFOV including Amplitude Doppler
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 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 8: Extended Field of View (EFOV), AKA Panoramic Imaging includes SonoCT imaging	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: X7-2t

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,12,13,14
	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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **EPIQ and EPIQ 7 Ultrasound System**

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	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: K172607, EPIQ/Affiniti	

System: **EPIQ and EPIQ 7 Ultrasound System**

Transducer: S8-3t

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: 10,11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note 10, 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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **EPIQ and EPIQ 7 Ultrasound System**

Transducer: X8-2ti

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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: XL14-3

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							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
Intra-luminal								
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Ultrasound System**

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: 5,8,10,11,12,13
	Intra-operative (Vascular)	P	P	P		P	Note: 1,3	Note: 5,8,10,11,12,13
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,17
	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: 5,8,9,10,11,12,13
	Adult Cephalic	P	P	P		P	Note: 1,3	Note: 8,10,11,12,13
	Trans-rectal	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,17
	Trans-vaginal	P	P	P		P	Note: 1,3	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: 1,3	Note: 5,6,8,9,10,11,12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,17
	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: 10,11,12,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Other (Fetal Echo)	P	P	P	P	P	Note: 1,2,3,4	Note: 5,6,8,10,12,13,14
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral Vascular	P	P	P		P	Note: 1,3	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 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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Ultrasound System**

Transducer: **C5-1**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,3	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: 5,6,8,9,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN		P	P	P		P	Note: 1,3
Other: Urology		P	P	P		P	Note: 1,3	Note: 5,6,8, 9,10,11,12,13,17
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,3	Note: 5,6,10,12,13
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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Ultrasound System**

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: 5,6,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN		P	P	P		P	Note: 1,3	Note: 5,6,7,8, 9,10,11,12,13
Other: Urology		P	P	P		P	Note: 1,3	Note: 5,6,8, 9,10,11,12,13
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							

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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Ultrasound System**

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,,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,11,12,13
	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: 5,6,8,9,11,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,3	Note: 5,6,8,9,11,12,13

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	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Ultrasound System**

Transducer: **C9-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,17
	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: 5,6,8,9,10,11,12,13,17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,17
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,17	
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,3	Note: 5,6,10,12,13
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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Ultrasound System**

Transducer: **C10-3v**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,3	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, 8,10,11,12,13, 15
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN		P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,11,12,13,15
Other: Urology		P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,11,12,13,15
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							

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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Ultrasound System**

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, 8,10,11,12,13
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN		P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,11,12,13
Other: Urology		P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,11,12,13
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,3	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	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Ultrasound System**

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, 8,10,11,12,13, 15
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,11,12,13,15	
Other: Urology	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,11,12,13,15	
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							

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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

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, 8,9,10,11,12,13,17
	Trans-vaginal	P	P	P		P	Note: 1,,3	Note: 5,6,7, 8,9,10,11,12,13,17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Intra-luminal								
Other: GYN								
Other: Urology	P	P	P		P	Note: 1,3	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: 5,6,8,10,11,12,13
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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

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: 5,6,8,9,10,11,13
	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: 5,6,8,9,10,11,13	
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	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	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Ultrasound System**

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							

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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

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							

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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

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	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **L12-3**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,11,12,13
	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: 5,6,8,9,10,11,12,13
	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: 5,6,8,9,10,11,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13
	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: 5,6,8,9,10,11,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,3	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	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Ultrasound System**

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: 5,6,7,8,9,10,11,12,13
	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: 5,6,8,9,10,11,12,13
	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: 5,6,8,9,10,11,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13
	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: 5,6,8,9,10,11,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,3	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	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Ultrasound System**

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, 8,9,10,11,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,17
	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: 5,6,8,9,10,11,12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,17
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral Vascular	P	P	P		P	Note: 1,3	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 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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Ultrasound System**

Transducer: **eL18-4**

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: 5,6,7,8,9,10,12,13,17
	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: 5,6,8,9,10,11,12,13,17
	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: 5,6,8,9,10,11,12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,17
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral Vascular	P	P	P		P	Note: 1,3	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 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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

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	P	P	P		P	Note: 1,3	Note: 5,6, 8,9,10,11,12,13
	Intra-operative (Cardiac)	P	P	P		P	Note: 1,3	Note: 5,8,9,10,11,12,13
	Intra-operative (Vascular)	P	P	P		P	Note: 1,3	Note: 5,8,9,10,11,12,13
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13
	Neonatal Cephalic							
	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: 5,6,8,9,10,11,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,3	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	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

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: 5,6,8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,3	Note: 5,6,8,10,11,12,13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,3	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	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Ultrasound System**

Transducer: **S5-1**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,3	Note: 5,6, 8,9,10,11,13,17
	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: 8,9,10,11,13,17
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,13,14
	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: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Ultrasound System**

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, 8,9,10,11,13
	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: 8,9,10,11,13
	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: 10,11,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,13,14
	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	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

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: 10,11,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,13,14
	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	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Ultrasound System**

Transducer: **S8-3t**

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: 10,11,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,13,14
	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	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Ultrasound System**

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: 7,8,9,10,13
	Abdominal	P	P	P		P	Note: 1,3	Note: 8,9,10,11,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 8,10,11,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	P	P	P		P	Note: 1,3	Note: 8,10,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P	P	P	Note: 1,3	Note: 10,11,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **S12-4**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,3	Note: 8,9,10,11,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 8,9,10,11,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	P	P	P		P	Note: 1,3	Note: 8,9,10,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,13,14
	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	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Ultrasound System**

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: 5,6,8,9,10,11,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,3	Note: 5,9,10,11,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **X7-2t**

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

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K172607, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Ultrasound System**

Transducer: X5-1

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 8,9,10,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 8,9,10,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,9,10,13
	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: 10,11,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,13,14
	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: K172607, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

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: 5,6,8,9,10,11,12,13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,3	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	
Previous Submission: K172607, EPIQ/Affiniti	

Philips Ultrasound, Inc.	Traditional 510(k) EPIQ and Affiniti Diagnostic Ultrasound Systems	Page 45 of 150
--------------------------	--	----------------

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.
22100 Bothell Everett Hwy
Bothell, WA 98021-8431

Contact person: Kym Rupp, Senior Regulatory Affairs Specialist
Email: kym.rupp@philips.com
Tel: 425-487-7127
Fax: 425-487-8666

Date prepared: April 23rd, 2018

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 Diagnostic Ultrasound System
EPIQ 7 Diagnostic Ultrasound System
EPIQ 5 Diagnostic Ultrasound System
Affiniti 70 Diagnostic Ultrasound System
Affiniti 50 Diagnostic Ultrasound System
Affiniti 30 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:

Predicate Device	510(k)
Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System	K172607

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

The intended use of the EPIQ, EPIQ 5, EPIQ7, Affiniti 30, Affiniti 50, and Affiniti 70 Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body with the follow Indications for Use:

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

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

When integrated with Philips EchoNavigator, the systems can assist the interventionalist and surgeon with image guidance during treatment of cardiovascular disease in which the procedure uses both live X-ray and live Echo Guidance.

The systems are intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information, and only for the purposes for which it was designed. However, nothing stated in the user

information reduces your responsibility for sound clinical judgement and best clinical procedure.

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 (K172607), employ the same fundamental scientific technology. The primary differences are the addition of the S9-2 transducer to the EPIQ Diagnostic Ultrasound Systems and the extended use of ElastQ Imaging Linear (Shear Wave Elastography Imaging). The main difference between ElastQ Imaging and the new ElastQ Imaging Linear is summarized below:

- ElastQ Linear enables a different scanning geometry. The cleared ElastQ Imaging uses curvilinear scanning geometry while ElastQ Imaging Linear uses Linear scanning geometry to allow for additional transducers to be used.
- The proposed ElastQ Imaging Linear has a higher spatial resolution which supports a stiffness range 0-200kPa (0-8.2 m/s). The cleared ElastQ Imaging supports a stiffness range of 0-90kPa (0-5.5 m/s). This expanded tissue stiffness range allows for measurements of the breast in addition to the abdomen.
- The proposed ElastQ Imaging Linear offers a visual comparison between compression elastography and ElastQ Linear images, which was not available on the currently cleared ElastQ Imaging

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 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.				
Standard Feature	EPIQ K172607 (Predicate Device)	EPIQ 3.0 (Proposed Device)	Affiniti K172607 (Predicate Device)	Affiniti 3.0 (Proposed Device)
Indications for Use	Fetal/Obstetric, Abdominal, Intraoperative (Vascular), Intraoperative (Cardiac), Pediatric, Small Organ (Breast, Thyroid, Testicle), Cephalic (Neonatal), Cephalic (Adult), Transrectal, Transvaginal	Same as EPIQ K172607	Same as EPIQ K172607	Same as EPIQ K172607

Philips Ultrasound, Inc.	Traditional 510(k) EPIQ and Affiniti Diagnostic Ultrasound Systems	Page 48 of 150
--------------------------	--	----------------

	Musculoskeletal (Conventional), Musculoskeletal (Superficial) Gynecological, Other: Urology, Cardiac Adult, Cardiac Pediatric, Transesophageal (Cardiac), Cardiac other (Fetal), Peripheral Vessel, Cerebral Vascular,			
Transducers	C5-1, C8-5, C9-2, C10-3v, C10-4ec, D2cwc, D5cwc, eL18-4, L12-3, L12-5 50, L15-7io, L18-5, S5-1, S7-3t, S8-3, S8-3t, S12-4, V6-2, X7-2t, X8-2t, D2tcd, X5-1, X6-1, VL13-5, X7-2, X8-2ti, XL14-3, 3D9-3v	Same as EPIQ K172607 with addition of the S9-2 transducer.	3D9-3v, C5-1, C6-2, C8-5, C9-2, C9-4V, C10-3v, C10-4ec, D2cwc, D2tcd, D5cwc, BP10-5ec, eL18-4, L12-3, L12-4, L12-5 50, L15-7io, L18-5, S4-2, S5-1, S7-3t, S8-3, S12-4, V6-2, VL13-5, X7-2t	Same as Affiniti K172607
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 K172607	<ul style="list-style-type: none"> • Phased array • Linear array • Curved array • Pencil Probes • Multi-plane Transesophageal • Motorized arrays 	Same as Affiniti K172607
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, CWD, Color Doppler, Combined modes,	Same	Same	Same
Shear wave Elastography	ElastPQ	Same	Same	Same
	ElastQ Imaging	Same with the addition of ElastQ Imaging Linear	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	IEC 60601-1 C22.2 No. 60601-1 ANSI/AAMI ES60601-1 IEC 60601-2-37	Same	Same	Same
EMC Compliance	IEC 60601-1-2	Same	Same	Same

Philips Ultrasound, Inc.	Traditional 510(k) EPIQ and Affiniti Diagnostic Ultrasound Systems	Page 49 of 150
--------------------------	--	----------------

Patient Contact Materials	No changes from EPIQ K172607			
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, 2014
- 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, Inc.	Traditional 510(k) EPIQ and Affiniti Diagnostic Ultrasound Systems	Page 50 of 150
--------------------------	--	----------------

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

- 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, 2014
- 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
- ISO 10993: Biological evaluation of medical devices, 2009.

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

Non-Clinical verification testing has been performed to cover system level requirements and the risk control measures in Appendix M. Non-Clinical validation testing covered the intended use and commercial claims as well as usability testing with representative intended users.

All these tests were used to support substantial equivalence of the subject device and demonstrate that the proposed **EPIQ and Affiniti Diagnostic Ultrasound Systems**:

- comply with the aforementioned international and FDA-recognized consensus standards and FDA ultrasound guidance document, and
- meet the acceptance criteria and are adequate for their intended use.

Therefore, the proposed **EPIQ and Affiniti Diagnostic Ultrasound Systems** are substantially equivalent to the predicate EPIQ and Affiniti Diagnostic Ultrasound Systems in terms of safety and effectiveness.

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

Philips Ultrasound, Inc.	Traditional 510(k) EPIQ and Affiniti Diagnostic Ultrasound Systems	Page 51 of 150
--------------------------	--	----------------

9. Clinical Data

The proposed **EPIQ and Affiniti Diagnostic Ultrasound Systems** did not require clinical studies since substantial equivalence to the currently marketed predicate devices, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System, 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 expanded use of ElastQ Imaging Linear mode and the new S9-2 transducer are substantially equivalent with regards to safety and effectiveness to the currently marketed predicate devices, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System and Philips 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.
- 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.

Philips Ultrasound, Inc.	Traditional 510(k) EPIQ and Affiniti Diagnostic Ultrasound Systems	Page 52 of 150
--------------------------	--	----------------

Sterilization Sites

Not applicable. No components are supplied sterile.

Track

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