



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

PHILIPS HEALTHCARE
C/O Mr. Mark Job
Responsible Third Party Official
1394 25th Street, NW
Buffalo MN 55313

October 4, 2017

Re: K172607

Trade/Device Name: Philips EPIQ 5 Diagnostic Ultrasound System, EPIQ 7 Diagnostic Ultrasound System, Affiniti 30 Diagnostic Ultrasound System, Affiniti 50 Diagnostic Ultrasound System, Affiniti 70 Diagnostic Ultrasound System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, ITX

Dated: August 28, 2017

Received: August 30, 2017

Dear Mr. Job:

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

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

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

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

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

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

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

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

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

Sincerely yours,



Robert Ochs
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)

K172607

Device Name

Philips EPIQ 5 Diagnostic Ultrasound System, EPIQ 7 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 series, Affiniti 30, Affiniti 50 and Affiniti 70 system is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following 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 system 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 judgment 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.

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DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

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

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

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

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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
 Transducer: **3D9-3v**

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

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

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

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	
Note 9: Color Power Angio (CPA)	
Previous Submission: K163120 EPIQ/Affiniti	

510(k) No: _____

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

Transducer: **C5-1**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8, 9,10,11,12,13,16,17,18
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, ,12,13,17,18
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN		P	P	P		P	Note: 1,2,3	Note: 5,6,7,8, 9,10,11,12,13, 17
Other: Urology		P	P	P		P	Note: 1,2,3	Note: 5,6,8, 9,10,,12,13, 17
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
Peripheral Vessel	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6,10,12,13
	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: K163120 EPIQ/Affiniti	Note 18: ElastQ Imaging

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No:

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

Transducer: **C8-5**

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

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

*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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

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

Transducer: **C9-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13, 17
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, ,12,13, 17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
Cardiac	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 Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6,10,12,13
	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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

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

Transducer: **C10-3v**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10, 11,12,13, 15, 17
	Trans-urethral							
Cardiac	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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
 System: **EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
 Transducer: **C10-4ec**
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13,17
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note: 1,2,3	Note: 5,6,7, 8,9,10, 11,12,13,17
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6,7, 8,9,10, 12,13,17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
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 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
	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
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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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
 System: **EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
 Transducer: D2cwc
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

General (Track I only)	Clinical Application 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			
Peripheral Vessel	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
	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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
 System: **EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
 Transducer: D2tcd
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

General (Track I only)	Clinical Application 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)							
Cardiac	Intra-luminal							
	Other: GYN							
Peripheral Vessel	Other: Urology							
	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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
 System: **EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
 Transducer: D5cwc
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

General (Track I only)	Clinical Application 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)							
Cardiac	Intra-luminal							
	Other: GYN							
Peripheral Vessel	Other: Urology							
	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
	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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

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

Transducer: L12-3

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 12,13, 17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 12,13, 17
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 12,13, 17
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 12,13, 17
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 12,13, 17
Cardiac	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	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 17
Vessel	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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
 System: **EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
 Transducer: L12-5 50
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N= new indication P= previously cleared
 Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

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

Transducer: L15-7i0

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	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
Cardiac	Intra-luminal							
	Other: GYN							
	Other: Urology							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
	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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 5 and EPIQ 7 Diagnostic 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	N	N	N		N	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal	N	N	N		N	Note: 1,2,3	Note: 5,6, 8,9,10,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,12,13,17
	Small Organ (breast, thyroid, testicle)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,12,13,17
	Musculo-skel. (Superficial)	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,12,13,17
Cardiac	Intra-luminal							
	Other: GYN							
	Other: Urology							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,12,13,17
	Cerebral Vascular	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,12,13,17

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: K163120, EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
 System: **EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
 Transducer: L18-5
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,,12,13,17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13,15,17
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,,12,13
Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,,12,13	
Cardiac	Intra-luminal							
	Other: GYN							
	Other: Urology							
	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
Peripheral Vessel	Other (Fetal Echo)							
	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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
System: **EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
Transducer: S5-1

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

General (Track I only)	Clinical Application 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)							
Cardiac	Musculo-skel. (Superficial)							
	Intra-luminal							
Peripheral Vessel	Other: GYN							
	Other: Urology							
	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	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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
 System: **EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
 Transducer: S7-3t
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

General (Track I only)	Clinical Application 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)							
Cardiac	Intra-luminal							
	Other: GYN							
	Other: Urology							
	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
Peripheral Vessel	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,,12,13,14
	Other (Fetal Echo)							
	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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____
 System: **EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
 Transducer: S8-3
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 7,8,10,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 7,8,10,,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,10,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
Cardiac	Intra-luminal							
	Other: GYN							
	Other: Urology							
	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
Peripheral Vessel	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
	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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

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

Transducer: S12-4

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

General (Track I only)	Clinical Application 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)							
Cardiac	Intra-luminal							
	Other: GYN							
Peripheral Vessel	Other: Urology							
	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							
	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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No:

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

Transducer: V6-2

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **VL13-5**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopple r**	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,,12,13
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,,12,13
	Intra-operative (<i>Cardiac</i>)							
	Intra-operative (<i>Vascular</i>)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,,12,13
	Small Organ (<i>breast, thyroid, testicle</i>)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,,12,13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,,12,13
Cardiac	Intra-luminal							
	Other: GYN							
	Other: Urology							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (Cardiac)							
	Other (<i>Fetal Echo</i>)							
	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 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No:

EPIQ 7 Diagnostic Ultrasound Systems

System:

X5-1

Transducer:

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: 8,9,10, ,12,13
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 8,9,10, 12,13
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal	P	P	P		P	Note: 1,2,3	Note: 8,9,10, 12,13
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
Other: GYN								
Other: Urology								
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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No:

EPiQ 7 Diagnostic Ultrasound Systems

System:

X6-1

Transducer:

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)							
Cardiac	Intra-luminal							
	Other: GYN	P	P	P		P	Note: 1,2,3	Note: ,6,8,9,10, 12,13
	Other: Urology							
	Cardiac Adult							
	Cardiac Pediatric							
Peripheral Vessel	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
	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: K163120 EPiQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **EPIQ 7 Diagnostic Ultrasound Systems**

Transducer: **X7-2**

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

Clinical Application		Mode of Operation (*Includes simultaneous B-mode)					
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler**	Combined (Spec.)
Ophthalmic	Ophthalmic						
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 6,7,8,10,,12,13
	Abdominal						
	Intra-operative (<i>Cardiac</i>)						
	Intra-operative (<i>Vascular</i>)						
	Laparoscopic						
	Pediatric	P	P	P		P	Note: 1,2,3
	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)						
Cardiac	Intra-luminal						
	Other: GYN						
	Other: Urology						
Peripheral Vessel	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4
	Trans-esophageal (Cardiac)						
	Other (<i>Fetal Echo</i>)	P	P	P	P	P	Note: 1,2,3,4
	Peripheral vessel						Note: 10,,13,14
	Cerebral Vascular						Note: 10,,13,14

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 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No:

EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems

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,,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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No:

EPIQ 7 Diagnostic Ultrasound Systems

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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **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: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **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	N	N	N	N	N	Note: 1,2,3,4	Note: 10,12,13,14
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)	N	N	N	N	N	Note: 1,2,3,4	Note: 10,12,13,14
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note 17: PercuNav
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **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)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17
	Cerebral Vascular	N	N	N		N	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 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 9: Color Power Angio (CPA)
Note 2: Combined modes include: B+M+Color Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 10: Harmonic Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 11: Contrast Imaging
Note 5: SonoCT	Note 12: 3D/4D Imaging
Note 6: Imaging for guidance of biopsy Note 7: Infertility monitoring of follicle development Note 8: Panoramic Imaging	Note 13: XRES
Previous Submission: K163120 EPIQ/Affiniti	Note 14: TDI
	Note 15: Elastography
	Note 16: ElastPQ (for Liver)
	Note 17: PercuNav

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note:17 PercuNav
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Diagnostic Ultrasound Systems**

Transducer: **C5-1**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)				
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*
Ophthalmic	Ophthalmic					
Fetal Imaging & Other	Fetal / OB	P	P	P		P
	Abdominal	P	P	P		P
	Intra-operative (Cardiac)					
	Intra-operative (Vascular)					
	Laparoscopic					
	Pediatric	P	P	P		P
	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)					
Cardiac	Intra-luminal					
	Other: GYN	P	P	P		P
	Other: Urology	P	P	P		P
	Cardiac Adult					
	Cardiac Pediatric					
Peripheral Vessel	Trans-esophageal (Cardiac)					
	Other (Fetal Echo)	P	P	P		P
	Peripheral Vessel					
	Cerebral Vascular					

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note:17 PercuNav
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **C6-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)				
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*
Ophthalmic	Ophthalmic					
Fetal Imaging & Other	Fetal / OB	P	P	P		
	Abdominal	P	P	P		Note: 1,3
	Intra-operative (Cardiac)					Note: 1,3
	Intra-operative (Vascular)					
	Laparoscopic					
	Pediatric	P	P	P		Note: 1,3
	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)					
Cardiac	Intra-luminal					
	Other: GYN	P	P	P		Note: 1,3
	Other: Urology	P	P	P		Note: 1,3
Peripheral Vessel	Cardiac Adult					
	Cardiac Pediatric					
	Trans-esophageal (Cardiac)					
	Other (Fetal Echo)	P	P	P		Note: 1,3
	Peripheral Vessel					
	Cerebral Vascular					

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **C8-5**

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Diagnostic Ultrasound Systems**

Transducer: **C9-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)				
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*
Ophthalmic	Ophthalmic					
Fetal Imaging & Other	Fetal / OB	P	P	P		
	Abdominal	P	P	P		Note: 1,3
	Intra-operative (Cardiac)					Note: 1,3
	Intra-operative (Vascular)					
	Laparoscopic					
	Pediatric	P	P	P		Note: 1,3
	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		Note: 1,3
	Musculo-skel. (Superficial)					
	Intra-luminal					
	Other: GYN	P	P	P		Note: 1,3
	Other: Urology					
Cardiac	Cardiac Adult					
	Cardiac Pediatric					
	Trans-esophageal (Cardiac)					
Peripheral Vessel	Other (Fetal Echo)	P	P	P		Note: 1,3
	Peripheral vessel					
	Cerebral Vascular					Note: 5,6,10,12,13

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note:17 PercuNav
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Diagnostic Ultrasound Systems**

Transducer: **C10-3v**

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

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

E = added via Appendix E, N= new indication. P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **3D9-3v**

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **C9-4v**

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

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

E = added via Appendix E

N= new indication

P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **C10-4ec**

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note:17 PercuNav
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic Ultrasound Systems**
 Transducer: **BP10-5ec**
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Diagnostic Ultrasound Systems**
Transducer: **D2cwc**

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic Ultrasound Systems**
 Transducer: **D2tcd**

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic Ultrasound Systems**
Transducer: **D5cwc**

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Diagnostic Ultrasound Systems**
Transducer: **L12-3**

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Diagnostic Ultrasound Systems**
Transducer: **L12-4**

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Diagnostic Ultrasound Systems**
Transducer: **L12-5 50**

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note:17 PercuNav
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **L15-7i0**

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

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

E = added via appendix E,N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

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

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: K163120, EPIQAffiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic Ultrasound Systems**
Transducer: **L18-5**

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70 Diagnostic Ultrasound Systems**
Transducer: **S5-1**

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

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

E = added via Appendix E, N= new indication, P= previously cleared
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	Note:17 PercuNav
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **S4-2**

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic Ultrasound Systems**
Transducer: **S7-3t**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)				
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*
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	Note: 1,2,3,4
	Cardiac Pediatric	P	P	P	P	Note: 1,2,3,4
	Trans-esophageal (Cardiac)	P	P	P	P	Note: 1,2,3,4
	Other (Fetal Echo)					
Peripheral Vessel	Peripheral vessel					
	Cerebral Vascular					

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Diagnostic Ultrasound Systems**
 Transducer: **S8-3**
 Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: _____

System: **Affiniti 70 Diagnostic Ultrasound Systems**

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,,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: K163120, EPIQ	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50 Diagnostic Ultrasound Systems**
 Transducer: **S12-4**

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

System: **Affiniti 70/50/30 Diagnostic Ultrasound Systems**
Transducer: **V6-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)				
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*
Ophthalmic	Ophthalmic					
Fetal Imaging & Other	Fetal / OB	P	P	P		Note: 1,3
	Abdominal					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: 1,3
Peripheral Vessel	Peripheral vessel					Note: 5,9,10,13
	Cerebral Vascular					

E = added via Appendix E,N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **X7-2t**

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

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

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic Imaging	
Previous Submission: K163120 EPIQ/Affiniti	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

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

Transducer: **VL13-5**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)				
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*
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
	Neonatal Cephalic					
	Adult Cephalic					
	Trans-rectal					
	Trans-vaginal					
	Trans-urethral					
	Trans-esoph. (non-Cardiac)					
	Musculo-skel. (Conventional)					
	Musculo-skel. (Superficial)					
	Intra-luminal					
Cardiac	Other: GYN					
	Other: Urology					
	Cardiac Adult					
	Cardiac Pediatric					
	Trans-esophageal (Cardiac)					
	Other (Fetal Echo)					
Peripheral Vessel	Peripheral vessel	P	P	P		P Note: 1,3
	Cerebral Vascular	P	P	P		P Note: 1,3

E = added via Appendix E, N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 9: Color Power Angio (CPA)
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 10: Harmonic Imaging
Note 2: Combined modes include: B+M+Color	Note 11: Contrast Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 12: 3D/4D Imaging
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 13: XRES
Note 5: SonoCT	Note 14: TDI
Note 6: Imaging for guidance of biopsy	Note 15: Elastography
Note 7: Infertility monitoring of follicle development	Note 16: ElastPQ (for Liver)
Note 8: Panoramic imaging	
Previous Submission: K163120 EPIQ/Affiniti	

510(k) Summary of Safety and Effectiveness

EPIQ and Affiniti Diagnostic Ultrasound Systems

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

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

Philips Ultrasound, Inc.
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Bothell, WA 98021-8431

Contact person: Maxs Newberry, Regulatory Affairs Engineer
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Date prepared: October 3, 2017

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:

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

These devices are classified as follows:

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

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

3. Substantially Equivalent Devices

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

Product		510(k)
Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System	Primary Predicate Device	K163120
Philips EchoNavigator	Predicate Device	K121781

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 series, Affiniti 30, Affiniti 50 and Affiniti 70 system is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following **Indications for Use**:

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

When Philips EPIQ system is 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 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.

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 (K163120), employ the same fundamental scientific technology. The primary differences are the addition of the eL18-4 transducer to the EPIQ and Affiniti Diagnostic Ultrasound Systems, the addition of the XL14-3 and X8-2ti

transducers to the EPIQ Diagnostic Ultrasound System, and the addition of a new EchoNavigator mode that allows compatibility with the Philips EchoNavigator software tool.

A comparison of the proposed **EPIQ and Affiniti Diagnostic Ultrasound Systems** to the currently marketed and predicate device, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System, and Philips EchoNavigator is provided in Table 1 below:

Table 1 Comparison of the proposed EPIQ and Affiniti Diagnostic Ultrasound Systems to the currently marketed and predicate device, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System, and Philips EchoNavigator.					
Standard Feature	Philips EchoNavigator (K121781) (Predicate device)	EPIQ K163120 (Primary Predicate Device)	EPIQ 1.8 (Proposed Device)	Affiniti K163120 (Primary Predicate Device)	Affiniti 1.8 (Proposed Device)
Indications for Use	EchoNavigator supports the interventionalist and surgeon in treatments where both live X-ray and live Echo guidance are used. The targeted patient population consists of patients with cardiovascular diseases requiring such a treatment.	Fetal/Obstetric, Abdominal, Intraoperative (Vascular), Intraoperative (Cardiac), Pediatric, Small Organ (Breast, Thyroid, Testicle), Cephalic (Neonatal), Cephalic (Adult), Transrectal, Transvaginal Musculoskeletal (Conventional), Musculoskeletal (Superficial) Gynecological, Other: Urology, Cardiac Adult, Cardiac Pediatric, Transesophageal (Cardiac), Cardiac other (Fetal), Peripheral Vessel, Cerebral Vascular,	Same as EPIQ K163120 but with the addition of integration with Philips EchoNavigator (K121781) software tool	Same as EPIQ K163120	Same as EPIQ K163120
Transducers	N/A	C5-1, C8-5, C9-2, C10-3v, C10-4ec, D2cwc, D5cwc, L12-3, L12-5 50, L15-7io, L18-5, S5-1, S7-3t, S8-3, S8-3t, S12-4, V6-2, X7-2t, X8-2t D2tcd, X5-1, X6-1, VL13-5, X7-2, 3D9-3v	Same as EPIQ K163120 with addition of eL18-4, XL14-3 and X8-2ti transducers	3D9-3v, C5-1, C6-2, C8-5, C9-2, C9-4V, C10-3v, C10-4ec, D2cwc, D2tcd, D5cwc, BP10-5ec, L12-3, L12-4, L12-5, L15-7io, L18-5, S4-2, S5-1, S7-3t, S8-3, S12-4, V6-2, VL13-5, X7-2t	Same as Affiniti K163120 with addition of the eL18-4 transducer

Table 1

Comparison of the proposed **EPIQ and Affiniti Diagnostic Ultrasound Systems** to the currently marketed and predicate device, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System, and Philips EchoNavigator.

Standard Feature	Philips EchoNavigator (K121781) (Predicate device)	EPIQ K163120 (Primary Predicate Device)	EPIQ 1.8 (Proposed Device)	Affiniti K163120 (Primary Predicate Device)	Affiniti 1.8 (Proposed Device)
Transducer Types	N/A	• Phased array • Linear array • Curved array • Pencil Probes • Multi-plane Transesophageal • Motorized arrays • 3D Matrix Array	Same as EPIQ K163120	• Phased array • Linear array • Curved array • Pencil Probes • Multi-plane Transesophageal • Motorized arrays	Same as Affiniti K163120
Transducer Frequency	N/A	1.0 – 18.0 MHz	Same	Same	Same
Acoustic Output Display & FDA Limits	N/A	IEC 62359 • ISPTA max=720 mw/cm2 • MI max =1.9 • MI display • TI display	Same	Same	Same
Imaging Mode	N/A	B mode, M mode, PWD, CWD, Color Doppler, Combined modes,	Same	Same	Same
Shear wave Elastography	N/A	ElastPQ	Same	Same	Same
	N/A	ElastQ Imaging	Same	NA	NA
# Transmit Channels	N/A	128	Same	Same	Same
# Receive Channels	N/A	256	Same	Same	Same
510(k) Track	N/A	Track 3	Same	Same	Same
Product Safety Certification	N/A	CSA International IEC 60601-1 C22.2 No. 60601-1 ANSI/AAMI ES60601-1 IEC 60601-2-37	Same	Same	Same
EMC Compliance	N/A	IEC 60601-1-2	Same	Same	Same
Patient Contact Materials	N/A	No changes from EPIQ K163120			

Table 1 Comparison of the proposed EPIQ and Affiniti Diagnostic Ultrasound Systems to the currently marketed and predicate device, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System, and Philips EchoNavigator.					
Standard Feature	Philips EchoNavigator (K121781) (Predicate device)	EPIQ K163120 (Primary Predicate Device)	EPIQ 1.8 (Proposed Device)	Affiniti K163120 (Primary Predicate Device)	Affiniti 1.8 (Proposed Device)
Accessories		• Various hardcopy, recording and printing devices: video thermal printer, report printer, DVD, USB • PercuNav Instruments • Biopsy guides • Footswitch	Addition of video switch for compatibility with EchoNavigator	Same	Same

7. Safety Considerations

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

The subject **EPIQ and Affiniti Diagnostic Ultrasound Systems** comply with the referenced standard as well as the FDA ultrasound guidance document, Guidance for Industry and FDA Staff – Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers, issued on September 9, 2008.

The system acoustic output limits are:

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

The system and transducers are compliant to:

- IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2007

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

8. Nonclinical Performance Data

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

- IEC 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2007
- IEC 60601-1-6 Medical Electrical Equipment – Part 1-6, General Requirements for Basic Safety and Essential Performance – Usability, 2010
- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2007
- ISO 10993: Biological evaluation of medical devices.

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

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 EchoNavigator mode and the new eL18-4, XL14-3 and X8-2ti transducers 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.

Sterilization Sites

Not applicable. No components are supplied sterile.

Track

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