November 9, 2018

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

Re: K182857
Trade/Device Name: EPIQ Diagnostic Ultrasound System, 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: Class II
Product Code: IYN, IYO, ITX
Dated: October 30, 2018
Received: November 2, 2018

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182857

Device Name

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

Indications for Use *(Describe)*

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

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

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

The systems are intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information, and only for the purposes for which it was designed. However, nothing stated in the user information reduces your responsibility for sound clinical 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: K182857

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

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,12,13,17
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12, 13,15,16,17,18, 19
	Intra-operative (Cardiac)	P	P	P	P	P	Note: 1,2,3	Note: 5,8,9,10, 12,13
	Intra-operative (Vascular)	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10, 12,13
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 12,13,17,18
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note:5,6,8,9,10,11,12,13,15,17, 19
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,12,13,17
	Adult Cephalic	P	P	P		P	Note: 1,2,3	Note: 8,9,10, 12,13,17
	Trans-rectal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 11,12,13,15,17
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10, 11,12,13,15,17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, ,12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, ,12,13,17
	Intra-luminal							
	Other: GYN	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,15,17
	Other: Urology	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,15,17
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10, ,12,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10, ,12,13,14
	Other (Fetal Echo)	P	P	P	P	P	Note: 1,2,3,4	Note: 5,6,8,10,12,13,14
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	Note: 1,2,3	Note: 5,6,8,9,10,11 ,12,13,17
	Cerebral vascular	P	P	P	P	P	Note: 1,2,3	Note: 5,6,8,9,10, 11,12,13,17

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

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

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

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

System: **EPIQ, 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, 910,11 ,12,13, 17
	Other: Urology	P	P	P		P	Note: 1,2,3	Note: 5,6,,8, 9,10, ,12,13, 17
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,6,10,12,13
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 11,12,13,17
	Cerebral vascular							

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: **C8-5**

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: **C9-2**

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: **C10-3v**

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857
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, 1112,13,17
	Trans-vaginal	P	P	P		P	Note: 1,2,3	Note: 5,6,7, 8,9,10, 12,13,17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10, 12,13,17
	Other: Urology	P	P	P		P	Note: 1,2,3	Note: 5,6,7,8,9,10,11,12,13,17
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,2,3	Note: 5,8,9,10,12,13
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10, 12,13, 17
	Cerebral Vascular							

N= new indication P= previously cleared
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: D2cwc

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: D2tcd

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: D5cwc

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

System: **EPIQ, 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 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: L15-7io

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

System: **EPIQ, 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							
	Abdominal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13
	Intra-operative (Cardiac)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 15,17,19
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,10,12,13, 17
	Neonatal Cephalic	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13, 15,17,19
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13,17
	Intra-luminal	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,12,13,17
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular	P	P	P		P	Note: 1,2,3	Note: 5,6,8,9,10,11,12,13,17

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: L18-5

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: S5-1

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: S7-3t

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: S8-3

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

System: **EPIQ, EPIQ 5 and EPIQ 7 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 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: S12-4

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

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857
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 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: **VL13-5**

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

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

N= new indication; P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857
System: **EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
Transducer: XL14-3
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N= new indication P= previously cleared
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857
System: **EPIQ, EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
Transducer: X5-1
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N= new indication P= previously cleared
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857
System: **EPIQ, EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
Transducer: X6-1
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N= new indication P= previously cleared
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

System: **EPIQ, EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
Transducer: **X7-2**
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N= new indication; P= previously cleared
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857
System: **EPIQ, EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
Transducer: X7-2t
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N= new indication P= previously cleared
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857
System: **EPIQ and EPIQ 7 Diagnostic Ultrasound Systems**
Transducer: X8-2t
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult	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 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857
System: **EPIQ 7 Diagnostic Ultrasound Systems**
Transducer: X8-2ti
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N= new indication P= previously cleared
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857
System: **EPIQ, EPIQ 5, and EPIQ 7 Diagnostic Ultrasound Systems**
Transducer: S9-2
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N= new indication P= previously cleared
Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857
System: **EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
Transducer: V9-2
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	N	N	N		N	Note: 1,2,3	Note: 5,6,8,9,10,12,13
	Abdominal	N	N	N		N	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)	N	N	N		N	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 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857
System: **EPIQ 5 and EPIQ 7 Diagnostic Ultrasound Systems**
Transducer: mC7-2
Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

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

N= new indication P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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: 5,6,8,9,10,1112,13,15,17
	Neonatal Cephalic	P	P	P		P	Note: 1,3	Note: 5,8,9,10,12,13
	Adult Cephalic	P	P	P		P	Note: 1,3	Note: 8,10,12,13
	Trans-rectal	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	Trans-vaginal	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13,15,17
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	Intra-luminal							
	Other: GYN	P	P	P		P		Note: 5,6,7,8,9,10,11,12,13, 15,17
	Other: Urology	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13, 15,17
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,12,13,14
	Trans-esophageal (Cardiac)	P	P	P	P	P	Note: 1,2,3,4	Note: 10,12,13,14
	Other (Fetal Echo)	P	P	P	P	P	Note: 1,2,3,4	Note: 5,6,8,10,12,13,14
Peripheral Vessel	Peripheral vessel	P	P	P	P	P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	Cerebral Vascular	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

System: **Affiniti 70 Diagnostic Ultrasound Systems**

Transducer: **C5-1**

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

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,3	Note: 5,6, 8,9,10,11,12,13,15
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN	P	P	P		P	Note: 1,3	Note: 5,6,7,8, 9,10,12,13
	Other: Urology	P	P	P		P	Note: 1,3	Note: 5,6,8, 9,10,12,13
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,3	Note: 5,6,10,12,13
Peripheral Vessel	Peripheral Vessel							
	Cerebral Vascular							

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

System: **Affiniti 70 Diagnostic Ultrasound Systems**

Transducer: **C9-2**

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

Clinical Application		Mode of Operation (*includes simultaneous B-mode)						
General (Track I only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Doppler*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	Abdominal	P	P	P		P	Note: 1,3	Note: 5,6, 8,9,10,11,12,13.17
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13,17
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,3	Note: 5.6,10,12,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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							

N= new indication. P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal	P	P	P		P	Note: 1,3	Note: 5,6,7, 8,10,12,13
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13
	Other: Urology	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)	P	P	P		P	Note: 1,3	Note: 5,6,8,10,12,13
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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*	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							

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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							

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: **BP10-5ec**

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

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal							
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult				P			
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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							

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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			

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: **L12-3**

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

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB	P	P	P		P	Note: 1,3	Note: 5,6,7,8,9,10,12,13
	Abdominal	P	P	P		P	Note: 1,3	Note: 5,6, 8,9,10,11,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Small Organ (breast, thyroid, testicle)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,11,12,13
	Neonatal Cephalic	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Musculo-skel. (Superficial)	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13
	Cerebral Vascular	P	P	P		P	Note: 1,3	Note: 5,6,8,9,10,12,13

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: **L15-7io**

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

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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	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, 8,9,10,12,13,17
	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)	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: 5,6,8,9,10,12,13,17

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: **L18-5**

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

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

System: **Affiniti 70 Diagnostic Ultrasound Systems**

Transducer: **S5-1**

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

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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*	Combined* (Spec.)	Other (Spec.)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal / OB							
	Abdominal	P	P	P		P	Note: 1,3	Note: 5,6, 8,9,10,12,13
	Intra-operative (Cardiac)							
	Intra-operative (Vascular)							
	Laparoscopic							
	Pediatric							
	Small Organ (breast, thyroid, testicle)							
	Neonatal Cephalic							
	Adult Cephalic	P	P	P		P	Note: 1,3	Note: 8,9,10,12,13
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Cardiac)							
	Musculo-skel. (Conventional)							
	Musculo-skel. (Superficial)							
	Intra-luminal							
	Other: GYN							
	Other: Urology							
Cardiac	Cardiac Adult	P	P	P	P	P	Note: 1,2,3,4	Note: 10,11,12,13,14
	Cardiac Pediatric	P	P	P	P	P	Note: 1,2,3,4	Note: 10,12,13,14
	Trans-esophageal (Cardiac)							
	Other (Fetal Echo)							
Peripheral Vessel	Peripheral vessel							
	Cerebral Vascular							

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: **S7-3t**

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

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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							

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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							

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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							

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: **VL13-5**

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

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

System: **Affiniti 70 Diagnostic Ultrasound Systems**

Transducer: X5-1

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

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: V9-2

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

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE STATEMENT

510(k) No: K182857

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

Transducer: mC7-2

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

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

N= new indication, P= previously cleared

Additional Comments:

*Color Doppler includes Color Amplitude Doppler	Note 10: Harmonic Imaging
Note 1: Combined modes include: B+PWD; B+Color; B+Amplitude; B+M	Note 11: Contrast Imaging
Note 2: Combined modes include: B+M+Color	Note 12: 3D/4D Imaging
Note 3: Combined modes include: B+Color+PWD; B+Amplitude+PWD	Note 13: XRES
Note 4: Combined modes include: B+CWD; B+Color+CWD; B+Amplitude+CWD	Note 14: TDI
Note 5: SonoCT	Note 15: Elastography
Note 6: Imaging for guidance of biopsy	Note 16: ElastPQ (for Liver)
Note 7: Infertility monitoring of follicle development	Note 17: PercuNav
Note 8: Panoramic Imaging	Note 18: ElastQ Imaging
Note 9: Color Power Angio (CPA)	Note 19: ElastQ Imaging Linear
Previous Submission: K181485	

K182857

510(k) Summary of Safety and Effectiveness

Philips EPIQ Diagnostic Ultrasound Systems and Philips 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.**

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Date prepared: September 17th, 2018

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

Common name: Diagnostic ultrasound system and transducers
Proprietary name: EPIQ Diagnostic Ultrasound System
EPIQ 7 Diagnostic Ultrasound System
EPIQ 5 Diagnostic Ultrasound System
Affiniti 70 Diagnostic Ultrasound System
Affiniti 50 Diagnostic Ultrasound System
Affiniti 30 Diagnostic Ultrasound System

These devices are classified as follows:

Classification Description	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 Philips EPIQ Diagnostic Ultrasound Systems and Philips Affiniti Diagnostic Ultrasound Systems are substantially equivalent to the following currently marketed devices:

Predicate Device	510(k)
Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System	K181485

Reference Device	510(k)
TOMTEC-ARENA TTA2	K150122

4. Device Description

The proposed Philips EPIQ Diagnostic Ultrasound Systems and Philips 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. Other than the introductions of the two new transducers, the device description, accessories and components are unchanged, reference table 1.

5. Indications for Use

The intended use of the EPIQ, EPIQ 5, EPIQ7, Affiniti 30, Affiniti 50, and Affiniti 70 Diagnostic Ultrasound Systems is diagnostic ultrasound imaging and fluid flow analysis of the human body with the 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 Philips EPIQ Diagnostic Ultrasound Systems and Philips Affiniti Diagnostic Ultrasound Systems can be used include Clinics, Hospitals, and clinical point-of-care for diagnosis of patients.

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

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

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

6. Technological Comparison to Predicate Devices

The proposed Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System and the currently marketed predicate device, Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System (K181485), employ the same fundamental scientific technology. The primary differences are the addition of the mC7-2 and V9-2 transducers to the Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound System.

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

TABLE 1

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

Standard Feature	EPIQ K181485 (Predicate Device)	EPIQ 4.0 (Proposed Device)	Affiniti K181485 (Predicate Device)	Affiniti 4.0 (Proposed Device)
Indications for Use	Fetal/Obstetric, Abdominal, Intraoperative (Vascular), Intraoperative (Cardiac), Pediatric, Small Organ (Breast, Thyroid, Testicle), Cephalic (Neonatal), Cephalic (Adult), Transrectal, Transvaginal Musculoskeletal (Conventional), Musculoskeletal (Superficial) Gynecological, Other: Urology, Cardiac Adult, Cardiac Pediatric, Transesophageal (Cardiac), Cardiac other (Fetal), Peripheral Vessel, Cerebral Vascular,	Same as EPIQ K181485	Same as EPIQ K181485	Same as EPIQ K181485
Transducers	C5-1, C8-5, C9-2, C10-3v, C10-4ec, D2cwc, D5cwc, eL18-4, L12-3, L12-5 50, L15-7io, L18-5, S5-1, S7-3t, S8-3, S8-3t, S12-4, V6-2, X7-2t, X8-2t, D2tcd, X5-1, X6-1, VL13-5, X7-2, X8-2ti, XL14-3, 3D9-3v	Same as EPIQ K181485 with addition of the V9-2 and cM7-2 transducers.	3D9-3v, C5-1, C6-2, C8-5,C9-2, C9-4V, C10-3v, C10-4ec, D2cwc, D2tcd, D5cwc, BP10-5ec, eL18-4, L12-3, L12-4, L12-5 50, L15-7io, L18-5, S4-2, S5-1, S7-3t, S8-3, S12-4, V6-2, VL13-5, X7-2t	Same as Affiniti K181485 with addition of the V9-2 and cM7-2 transducers.

Transducer Types	▪ Phased array ▪ Linear array ▪ Curved array ▪ Pencil Probes ▪ Multi-plane Transesophageal ▪ Motorized arrays ▪ 3D Matrix Array	Same as EPIQ K181485, both the V9-2 and mC7-2 are curved array transducers	▪ Phased array ▪ Linear array ▪ Curved array ▪ Pencil Probes ▪ Multi-plane Transesophageal ▪ Motorized arrays	Same as EPIQ K181485, both the V9-2 and mC7-2 are curved array transducers
Transducer Frequency	1.0 – 18.0 MHz	Same	Same	Same
Acoustic Output Display & FDA Limits	IEC 62359 ▪ ISPTA max=720 mw/cm2 ▪ MI max =1.9 ▪ MI display ▪ TI display	Same	Same	Same
Imaging Mode	B mode, M mode, PWD, CWD, Color Doppler, Combined modes,	Same	Same	Same
Shear wave Elastography	ElastPQ	Same	Same	Same
	ElastQ Imaging	Same	NA	NA
	ElastQ Imaging Linear	Same		
# Transmit Channels	128	Same	Same	Same
# Receive Channels	256	Same	Same	Same
510(k) Track	Track 3	Same	Same	Same
Product Safety Certification	IEC 60601-1 C22.2 No. 60601-1 ANSI/AAMI ES60601-1 IEC 60601-2-37	Same	Same	Same
EMC Compliance	IEC 60601-1-2	Same	Same	Same
Patient Contact Materials	Same- See section 1.7.3 for an analysis of patient contacting material			
Accessories	▪ Various hardcopy, recording and printing devices: video thermal printer, report printer, DVD, USB ▪ PercuNav Instruments ▪ Biopsy guides ▪ Footswitch	Same	Same	Same
Rendering Enhancements	▪ TrueVue / GlassVue ▪ aReveal ▪ MaxVue ▪ QuickVue ▪ TrueVue ▪ MultiVue	Same with the addition of FlexVue and Needle Visualization	Same	Same with the addition of FlexVue and Needle Visualization
QLAB Apps	▪ 3DQ 3DQ Advanced ▪ GI 3DQ MVN ▪ A2DQ aCMQ ▪ CMQ Stress ▪ IMT MVI ▪ ROI SQ ▪ Heartmodel ▪ Dynamic Heartmodel	AutoStrain (reference K151022)	• ROI IMT • MVI GI 3DQ • VPQ SQ • A2DQ aCMQ • MVN	Same

7. Safety Considerations

As a Track 3 ultrasound device, the subject Philips EPIQ Diagnostic Ultrasound System and Philips Affiniti Diagnostic Ultrasound Systems are designed to comply with the acoustic output display requirements of IEC 60601-2-37 Ed 2.1 (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 devices, Philips EPIQ Diagnostic Ultrasound Systems and Philips 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 identical to the previous version and are:

- Ispta.3 ≤ 720 MW/cm^2
- MI ≤ 1.9
- TI ≤ 6.0

The system and transducers are compliant to:

- ANSI/AAMI 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2014
- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2015
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017

8. Nonclinical Performance Data

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

- ANSI/AAMI 60601-1: Medical electrical equipment. General requirements for basic safety and essential performance, 2005, Amendment 1, 2012
- IEC 60601-1-2 Medical Electrical Equipment – Part 1-2, General Requirements for Basic Safety and Essential Performance – Collateral Standard Electromagnetic Compatibility, 2014
- IEC 60601-2-37: Medical electrical equipment. Particular requirements for the

basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2015
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields, 2017
- ISO 10993: Biological evaluation of medical devices, 2009.

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

All testing was used to support substantial equivalence of the subject device and demonstrate that the proposed Philips EPIQ Diagnostic Ultrasound Systems and Philips 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 Philips EPIQ Diagnostic Ultrasound Systems and Philips Affiniti Diagnostic Ultrasound Systems are substantially equivalent to the predicate Philips EPIQ Diagnostic Ultrasound Systems and Philips 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 Philips EPIQ Diagnostic Ultrasound Systems and Philips Affiniti Diagnostic Ultrasound Systems did not require clinical studies since substantial equivalence to the currently marketed predicate devices has been established.

10. Conclusion

For these tests, all pre-determined acceptance criteria were met. The results of these tests show that the proposed Philips EPIQ Diagnostic Ultrasound Systems and Philips Affiniti Diagnostic Ultrasound Systems with the new V9-2 and mC7-2 transducers met their intended use. The predicate device and the proposed Philips EPIQ Diagnostic Ultrasound Systems and Philips Affiniti Diagnostic Ultrasound Systems:
- indicated for the diagnostic ultrasonic imaging and fluid flow analysis.
- have the same gray-scale and Doppler capabilities.

- use essentially the same technologies for imaging, Doppler functions and signal processing.
- have acoustic output levels within the Track 3 FDA limits.
- manufactured under equivalent quality systems.
- manufactured of materials with equivalent bio safety.
- designed and manufactured to the same electrical and physical safety standards.

The differences between the predicate and subject device do not raise new questions of safety and/or effectiveness and support a determination of substantial equivalence.

514 Performance Standards

There are no Sec. 514 performance standards for the proposed Philips EPIQ Diagnostic Ultrasound Systems and Philips Affiniti Diagnostic Ultrasound Systems.

Prescription Status

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