DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Carestream Health, Inc.
% Ms. Carolyn Wagner
Supervising Sr. Manager, Regulatory Affairs & Quality Systems
150 Verona Street
ROCHESTER NY 14608

December 9, 2015

Re: K152467
Trade/Device Name: Touch Ultrasound
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: November 5, 2015
Received: November 9, 2015

Dear Ms. Wagner:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Robert Ochs, 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: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K152467

Device Name

Touch Ultrasound

Indications for Use *(Describe)*

Ultrasound scanner and transducers for B, Tissue and Contrast Harmonic Imaging, M, PWD, CWD, Color Doppler, Vector Flow Imaging and combined mode imaging and Elastography.

Signal Analysis.

Guidance of biopsy needles, geometrical measurements and calculation of parameters. And optimal 3-D unit can reconstruct a series of 2-D images into a single 3-D volume and display this on the screen.

An optional Vector Flow Imaging (VFI) module: Color Flow Mapping (CFM) imaging mode with the ability to visualize both the axial and the transverse velocity.

Clinical Applications:

- Fetal (Sometimes called Obstetrics)
- Abdominal
- Intra-operative
- Intra-operative (Neuro) (sometimes called Neuro Surgical)
- Pediatrics
- Small Organ (Sometimes called Small Parts)
- Neonatal Cephalic (Cephalic is sometimes called trans-cranial)
- Adult Cephalic (Cephalic is sometimes called trans-cranial)
- Trans-rectal
- Trans-vaginal
- Trans-urethral
- Musculo-skeletal (Conventional)
- Musculo-skeletal (Superficial)
- Cardiac Adult
- Peripheral Vessel (Sometimes called Peripheral Vascular)

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)

PLEASE DO NOT WRITE BELOW THIS LINE CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

System: Touch Ultrasound

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD 25)	Tissue Harmonic Imaging	Contrast Harmonic Imaging 26)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)	P	P	P	N	P	N	P	P		P	N24)
Abdominal 3)	P	P	P	N	P	N	P	P		P	N24)
Intra-operative (Specify 4)	P	P	P	N	P	N	P	P		P	N24)
Intra-operative (Neuro 5)	P	P	P	N	P	N	P	P		P	N24)
Laparoscopic 6)											
Pediatric 7)	P	P	P	N	P	N	P	P		P	N24)
Small Organ (Specify 8)	P	P	P	N	P	N	P	P		P	N24)
Neonatal Cephalic 9)	P	P	P	N	P	N	P	P		P	N24)
Adult Cephalic 10)	P	P	P	N	P	N	P	P		P	N24)
Trans-rectal 11)	P	P	P	N	P	N	P	P		P	N24)
Trans-vaginal 12)	P	P	P	N	P	N	P	P		P	N24)
Trans-urethral 13)	P	P	P	N	P	N	P	P		P	N24)
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)	P	P	P	N	P	N	P	P		P	N24)
Musculo-skel. (Superficial 16)	P	P	P	N	P	N	P	P		P	N24)
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)	P	P	P	N	P	N	P	P		P	
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)	P	P	P	N	P	N	P	P		P	N23) N24)
Other (Specify 24)											N

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging. Tissue Harmonic Imaging.

The numbering in the table above refers to the comments provided below and, in case it is considered relevant, further comments and history in the Attachment 006_Instructions For Use - Attachment.
Please do observe that the numbering from 1 to 24 is fixed to make the document more consistent meaning that comments are only provided in the table below if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD. C: Color Flow mapping Doppler incl. Amplitude(power)Doppler

23) Vector Flow Imaging (VFI)
24) Elastography.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

System: Touch Ultrasound

Transducer: 9018

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD	Tissue Harmonic Imaging	Contrast Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)	P	P	P		P		P	P		P	N24)
Trans-vaginal 12)	P	P	P		P		P	P		P	N24)
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											N

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging. Tissue Harmonic Imaging.

The numbering in the table above refers to the comments provided below and, in case it is considered relevant, further comments and history in the Attachment 006_Instructions For Use - Attachment.
Please do observe that the numbering from 1 to 24 is fixed to make the document more consistent meaning that comments are only provided in the table below if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD. C: Color Flow mapping Doppler incl. Amplitude(power)Doppler

24) Elastography.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

System: Touch Ultrasound

Transducer: 9051

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD	Tissue Harmonic Imaging	Contrast Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)	P	P	P		P		P	P		P	N24)
Small Organ (Specify 8)	P	P	P		P		P	P		P	N24)
Neonatal Cephalic 9)											
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)	P	P	P		P		P	P		P	N24)
Musculo-skel. (Superficial 16)	P	P	P		P		P	P		P	N24)
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)	P	P	P		P		P	P		P	N23) N24)
Other (Specify 24)											N

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging. Tissue Harmonic Imaging.

The numbering in the table above refers to the comments provided below and, in case it is considered relevant, further comments and history in the Attachment 006_Instructions For Use - Attachment.
Please do observe that the numbering from 1 to 24 is fixed to make the document more consistent meaning that comments are only provided in the table below if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD. C: Color Flow mapping Doppler incl. Amplitude(power)Doppler

23) Vector Flow Imaging (VFI)
24) Elastography.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

System: Touch Ultrasound

Transducer: 9062

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD 25)	Tissue Harmonic Imaging	Contrast Harmonic Imaging 26)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)											
Intra-operative (Specify 4)	P	P	P		P		P	P		P	N24)
Intra-operative (Neuro 5)	P	P	P		P		P	P		P	N24)
Laparoscopic 6)											
Pediatric 7)	P	P	P		P		P	P		P	N24)
Small Organ (Specify 8)											
Neonatal Cephalic 9)	P	P	P		P		P	P		P	N24)
Adult Cephalic 10)											
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)											
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											N

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging. Tissue Harmonic Imaging.

The numbering in the table above refers to the comments provided below and, in case it is considered relevant, further comments and history in the Attachment 006_Instructions For Use - Attachment.
Please do observe that the numbering from 1 to 24 is fixed to make the document more consistent meaning that comments are only provided in the table below if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD. C: Color Flow mapping Doppler incl. Amplitude(power)Doppler

24) Elastography.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

System: Touch Ultrasound

Transducer: 9077

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

Clinical Application	Modes										
Specific (Tracks I & III)	B	M	PWD	CWD 25)	Tissue Harmonic Imaging	Contrast Harmonic Imaging 26)	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined 1)	Other
Ophthalmic											
Fetal 2)											
Abdominal 3)	P	P	P	N	P		P	P		P	
Intra-operative (Specify 4)											
Intra-operative (Neuro 5)											
Laparoscopic 6)											
Pediatric 7)											
Small Organ (Specify 8)											
Neonatal Cephalic 9)											
Adult Cephalic 10)	P	P	P	N	P		P	P		P	
Trans-rectal 11)											
Trans-vaginal 12)											
Trans-urethral 13)											
Trans-esoph. (non-Card.) 14)											
Musculo-skel. (Conventional 15)											
Musculo-skel. (Superficial 16)											
Intra-luminal 17)											
Other (Specify 18)											
Cardiac Adult 19)	P	P	P	N	P		P	P		P	
Cardiac Pediatric 20)											
Trans-esoph. (Cardiac 21)											
Other (Specify 22)											
Peripheral vessel 23)											
Other (Specify 24)											

N= new indication; P= previously cleared by FDA; E= added under Appendix E
*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging. Tissue Harmonic Imaging.

The numbering in the table above refers to the comments provided below and, in case it is considered relevant, further comments and history in the Attachment 006_Instructions For Use - Attachment.
Please do observe that the numbering from 1 to 24 is fixed to make the document more consistent meaning that comments are only provided in the table below if relevant.

Additional Comments:

1.	Mode combinations:	B+M, B+D, B+C, B+D+C. B includes Tissue Harmonic Imaging D:PWD. C: Color Flow mapping Doppler incl. Amplitude(power)Doppler

25) Continuous Wave Doppler (CWD/CW)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Prescription Use (Per 21 CFR 801.109)

DIAGNOSTIC ULTRASOUND INDICATIONS FOR USE FORM

System: bk2300_____

Transducer: 9022 (Product Name 10L2w) _____

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

Clinical Application Specific	B	M	PWD	CW	Tissue Harmonic Imaging	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (Specify 1)	Other
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)										
Intra-operative (Neuro)										
Laparoscopic										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Trans-rectal										
Trans-vaginal										
Trans-urethral										
Trans-esoph. (non-Card.)										
Musculo-skel. (Conventional)										
Musculo-skel. (Superficial)										
Intra-luminal										
Other (Specify)										
Cardiac Adult										
Cardiac Pediatric										
Trans-esoph. (Cardiac)										
Other (Specify)										
Peripheral vessel	N	N	N	N	N	N	N		N	
Other (Specify) 2)										N

N= new indication; P= previously approved.

*Examples may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, Color Velocity Imaging. Tissue Harmonic Imaging.

Additional Comments:

1) Mode combinations:
   B+M, B+D, B+C, B+D+C. (D is PWD, C is Color Flow mapping Doppler including Amplitude(power)Doppler)

2) Elastography

510(k) Summary:

This summary is provided as part of this Premarket Notification in compliance with 21CRF, Section 807.92.

Submitters name: Carestream Health, Inc.
Address: 150 Verona St., Rochester, NY 14608
Phone: 585-627-6588
Fax: 585-323-7643
Contact person: Carolyn Wagner, Sr. Supervising Manager, Regulatory Affairs & Quality Systems
Date prepared: August 25, 2015

Trade name: Touch Ultrasound
Common name: Diagnostic Ultrasound System
Classification names:

Ultrasonic Pulsed Echo Imaging System	(90 IYO, CFR 892.1560)
Ultrasonic Pulsed Doppler Imaging System	(90 IYN, CFR 892.1550)
Diagnostic Ultrasonic Transducer	(90 ITX, CFR 892.1570)

Identification of predicate, legally marketed devices:
B-K Medical Ultrasound Scanner Pro Focus 2202, K043524
B-K Medical Ultrasound Scanner Pro Focus 2202, K100919
BK Medical Ultrasound Scanner bk2300, K140428
Carestream Health Touch Ultrasound, K150342
Siemens Ultrasound Scanner System Acuson S1000, K130619

Device description:
Ultrasound scanner and transducers for B, Tissue and Contrast Harmonic Imaging, M, PWD, CWD, Color Doppler, Smart Flow Imaging, combined mode imaging, and Elastography.

Signal Analysis.

Guidance of biopsy needles, geometrical measurements and calculation of parameters. A 3-D unit that can reconstruct a series of 2-D images into a single 3-D volume and display this on the screen.

An optional Smart Flow Imaging module: Color Flow Mapping (CFM) imaging mode with the ability to visualize both the axial and the transverse velocity.

Optional wireless functionality.

Transducers

All the transducers in this submission have previously been cleared by FDA.

In this 510(k) application the new modes:

1) Elastography
2) Smart Flow Imaging (referred to as Vector Flow Imaging [VFI] in K100919)
3) Continuous Wave Doppler (CWD/CW)
4) Contrast Harmonic Imaging (CHI or Ci)

have been added to the functionality of relevant transducers as indicated in the Instructions For Use Section in VOL_004.

There are no changes to the physical design of the transducers.

There are no changes to the patient contact materials. All patient contact materials are biocompatible.

All transducers used together withTouch Ultrasound are Track 3 transducers.

Acoustic output

The system controlling the Acoustic Output in the modified Touch US is the same as the system in the predicate device Pro Focus 2202. The system will assure that the acoustic output always will stay below the pre-amendments upper limits i.e. Ispta ≤ 720 mW/cm² and MI ≤ 1.9 (Track 3, non ophthalmic).

The Thermal Index values are maximum 6.0, i.e. TI ≤ 6.0

Clinical measurement accuracy

Clinical measurements and calculations are described and accuracies are provided in the User Information.

Thermal, mechanical and electrical safety.

The ultrasound scanner system Touch Ultrasound has been tested by a recognized Certified Body.

Acoustic Output Reporting

The Acoustic Output Reporting is made according to the standards required by "Information for Manufacturers Seeking Clearance of Diagnostic Ultrasound Systems and Transducers, FDA, CDRH, September 9, 2008".

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of the human body.

Summary of Technological Characteristics - Predicate Devices Compared to Modified Device

Devices and Predicates	Predicate Device K150342, Touch Ultrasound	Predicate Device K140428, Ultrasound scanner bk2300	Predicate Device K043524, Ultrasound scanner Pro Focus 2202	Predicate Device K100919, Ultrasound scanner Pro Focus 2202	Predicate Device K130619, Ultrasound scanner system Acuson S1000	Modified Device (this application), Touch Ultrasound
Modes of operation Ref: [1] Appendix G	B	B	B	B	B	B
	THI	THI	THI	THI	THI	THI
	M,	M,	M,	M,	M,	M,
	PWD,	PWD,	PWD,	PWD,	PWD,	PWD,
	CFM[1)]	CFM[1)]	CFM[1)]	CFM[1)]	CFM[1)]	CFM[1)]
	and combinations	and combinations	and combinations	and combinations	and combinations	and combinations
			CHI			CHI
			CWD,			CWD,
				VFI		Smart Flow Imaging
					Elastography	Elastography
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:
Indications for Use	Fetal (incl Obstetrics)	Fetal (incl Obstetrics)	Fetal (incl Obstetrics)	Fetal (incl Obstetrics)	Fetal (incl Obstetrics)	Fetal (incl Obstetrics)
	Abdominal	Abdominal	Abdominal	Abdominal	Abdominal	Abdominal
	Intraoperative	Intraoperative	Intraoperative	Intraoperative	Intraoperative	Intraoperative
	Neurosurgery	Neurosurgery	Neurosurgery	Neurosurgery	Neurosurgery	Neurosurgery
	Pediatrics	Pediatrics	Pediatrics	Pediatrics	Pediatrics	Pediatrics

	Small Parts (organs)	Small Parts (organs)	Small Parts (organs)	Small Parts (organs)	Small Parts (organs)	Small Parts (organs)
	Adult Cephalic	Adult Cephalic	Adult Cephalic	Adult Cephalic	Adult Cephalic	Adult Cephalic
	Neonatal Cephalic	Neonatal Cephalic			Neonatal Cephalic	Neonatal Cephalic
	Transrectal	Transrectal	Transrectal	Transrectal	Transrectal	Transrectal
	Transvaginal	Transvaginal	Transvaginal	Transvaginal	Transvaginal	Transvaginal
	Transurethral	Transurethral	Transurethral	Transurethral	Transurethral	Transurethral
	Muskulo-skeletal (conventional and superficial)	Muskulo-skeletal (conventional and superficial)	Muskulo-skeletal (conventional and superficial)	Muskulo-skeletal (conventional and superficial)	Muskulo-skeletal (conventional and superficial)	Muskulo-skeletal (conventional and superficial)
	Cardiac	Cardiac	Cardiac	Cardiac	Cardiac	Cardiac
	Peripheral Vessel	Peripheral Vessel	Peripheral Vessel	Peripheral Vessel	Peripheral Vessel	Peripheral Vessel
Features			ECG (not monitoring)	ECG (not monitoring)		

1) CFM - Color Flow Mapping = Color Doppler and Amplitude (Power) Doppler.

A brief discussion of non-clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.
The device has been evaluated for acoustic output, thermal, electrical, electromagnetic and mechanical safety, biocompatibility and has been found to conform with applicable medical device safety standards. The system complies with the following voluntary standards:

- AIUM/NEMA UD-2, Acoustic Output Measurement Standard For Diagnostic Ultrasound Equipment
- AIUM/NEMA UD-3, Real-time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 60601-1, Medical Electrical Equipment, Part 1: General requirements for safety
- IEC 60601-1-2, General requirements for safety, Collateral Standard, Electromagnetic Compatibility – Requirements and tests
- IEC 60601-2-37, Particular requirements for the safety of ultrasonic diagnostic medical and monitoring equipment
- ISO 14971, Application of Risk Management of Medical Devices
- EN ISO 10993-1, Biocompatibility
- IEC 62304, Medical Device Software – Software lifecycle processes
- IEC 62359, Ultrasonics – Field characterization – Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields

Thermal, electrical, electromagnetic, mechanical and biocompatibility safety is unchanged.

Technological characteristics compared to the predicate device
The predicate devices have the same major technological characteristics as the subject device described above.

Minor differences with respect to the Ultrasound Scanner System consist of: Addition of new modes.