



December 13, 2019

Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
% Zhang Wei
Engineer of Technical Regulation
Keji 12th Road South, Hi-tech Industrial Park
Shenzhen, Guangdong 518057
CHINA

Re: K192152

Trade/Device Name: DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/
DC-TV/DC-TQ 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 and LLZ

Dated: October 30, 2019

Received: November 21, 2019

Dear Zhang Wei:

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/pmnm.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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K192152

Device Name

DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System

Indications for Use (Describe)

The DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intra-operative (abdominal, thoracic, and vascular), pediatric, small organ(breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(adult, pediatric) , trans-esoph. (Cardiac), peripheral vessel, and urology exams.

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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System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System								
Transducer:	/								
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2,3, 4,6,7,13
	Abdominal	P	P	P	P	P	P	P	Note 1, 2, 3,4,6,7,10,11,12,13,14
	Intra-operative (Specify*)	P	P	P		P	P	P	Note1,2,4
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1, 2,3, 4,6,7,13
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,7,8,11,12,13
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1,2, 4,6,7,13
	Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2,4, 6,7,13
	Trans-rectal	P	P	P		P	P	P	Note 1, 2,3, 4,6,7,8
	Trans-vaginal	P	P	P		P	P	P	Note 1, 2,3, 4,6,7,8,14
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P	P	P	P	P	Note 1, 2, 4,6,7,8,11,12,13
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2, 4,7,8,11,12,13
Intravascular									
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7,9,13
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7,13
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)	P	P	P	P	P	P	P	Note 1, 5,6
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P	N	P	P	P	Note 1, 2, 4,6,7,13
	Other (Specify***)	P	P	P		P	P	P	Note 1, 2, 4,6,7
N=new indication; P=previously cleared by FDA; E=added under Appendix E									
Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.									
*Intraoperative includes abdominal, thoracic, and vascular									
**Small organ-breast, thyroid, testes.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.									
Note 2: Smart3D									
Note 3:4D(Real-time 3D)									
Note 4: iScape									
Note 5: TDI									
Note 6: Color M									
Note 7: Biopsy Guidance									
Note 8: Strain Elastography									
Note 9: Contrast imaging(contrast agent for LVO)									
Note 10: Contrast imaging (Contrast agent for Liver)									
Note 11: STE									
Note 12: STQ									
Note 13: Ultrasound Fusion Imaging									
Note 14: GYN/Pelvic									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System										
Transducer:	C5-1E										
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:										
Clinical Application		Mode of Operation									
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)		
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 4,6,7,13		
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4,6,7,10,11,12,13,14		
	Intra-operative (Specify*)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4,6,7,13		
	Small Organ (Specify**)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4,6,7,13		
	Musculo-skeletal (Superficial)										
Intravascular											
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intravascular (Cardiac)										
	Trans-esoph. (Cardiac)										
	Intra-cardiac										
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,6,7,13		
	Other (Specify***)										
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E											
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.											
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System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System								
Transducer:	L14-5WE								
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1,2, 4,7,13
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1,2, 4,7,13
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,7,8,11,12,13
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,7,13
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2, 4,7,11,12,13
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2, 4,7,11,12,13
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2, 4,7,13
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E									
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Transducer:	L9-3E										
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:										
Clinical Application		Mode of Operation									
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)		
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4,7,10		
	Intra-operative (Specify*)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4,7		
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,7,8,11,12		
	Neonatal Cephalic	P	P	P		P	P	P	Note 1, 2, 4,7		
	Adult Cephalic										
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4,7,11,12		
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1, 2, 4,7,11,12		
Intravascular											
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intravascular (Cardiac)										
	Trans-esoph. (Cardiac)										
	Intra-cardiac										
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,7		
	Other (Specify***)										
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Transducer:	V11-3HE										
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:										
Clinical Application		Mode of Operation									
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)		
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 4,6,7		
	Abdominal										
	Intra-operative (Specify*)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Specify**)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal	P	P	P		P	P	P	Note 1, 2, 4,6,7,8		
	Trans-vaginal	P	P	P		P	P	P	Note 1, 2, 4,6,7,8,14		
	Trans-urethral										
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	Intra-cardiac										
Peripheral vessel	Peripheral vessel										
	Other (Specify***)	P	P	P		P	P	P	Note 1, 2, 4,6,7		
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System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	D8-2E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 3, 4, 6,7	
	Abdominal	P	P	P		P	P	P	Note 1, 3, 4, 6,7,14	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
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	Other (Specify***)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	D7-2E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 3, 4, 6	
	Abdominal	P	P	P		P	P	P	Note 1, 3, 4, 6, 14	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
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Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.										
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Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	C7-3E									
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Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
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Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 4,6,7	
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4,6,7,10,14	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4,6,7	
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Intravascular									
	Cardiac	Cardiac Adult								
Cardiac Pediatric										
Intravascular (Cardiac)										
Trans-esoph. (Cardiac)										
Intra-cardiac										
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,6,7	
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	L12-3E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4,7	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4,7	
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,7,8,11,12	
	Neonatal Cephalic	P	P	P		P	P	P	Note 1, 2, 4,7	
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4,7,11,12	
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1, 2, 4,7,11,12	
Cardiac	Intravascular									
	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
Peripheral vessel	Intra-cardiac									
	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,7	
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	DE11-3E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 3,4,6,7	
	Abdominal									
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal	P	P	P		P	P	P	Note 1, 3,4,6,7,8	
	Trans-vaginal	P	P	P		P	P	P	Note 1, 3,4,6,7,8,14	
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Cardiac	Intravascular									
	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
Peripheral vessel	Intra-cardiac									
	Peripheral vessel									
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System								
Transducer:	SP5-1E								
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P	P	P	P	P	Note 1, 2,4, 6,7,13
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	P	P	P	P	Note 1, 2,4, 6,7,13
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2,4, 6,7,13
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Intravascular									
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7,9,13
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7,13
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel								
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E									
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.									
*Intraoperative includes abdominal, thoracic, and vascular									
**Small organ-breast, thyroid, testes.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.									
Note 2: Smart3D									
Note 3:4D(Real-time 3D)									
Note 4: iScape									
Note 5: TDI									
Note 6: Color M									
Note 7: Biopsy Guidance									
Note 8: Strain Elastography									
Note 9: Contrast imaging(contrast agent for LVO)									
Note 10: Contrast imaging (Contrast agent for Liver)									
Note 11: STE									
Note 12: STQ									
Note 13: Ultrasound Fusion Imaging									
Note 14: GYN/Pelvic									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of Device Evaluation(ODE)									

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	SC5-1E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 4,6,7,13	
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4,6,7,10,11,12,13,14	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4,6,7,13	
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4,6,7,13	
	Musculo-skeletal (Superficial)									
Intravascular										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,6,7,13	
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	D6-2NE									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note1,3, 4,6	
	Abdominal	P	P	P		P	P	P	Note1,3, 4,6,14	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P	Note1,3, 4,6	
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Intravascular										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel									
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	C6-2GE									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note1,2,4,6,7	
	Abdominal	P	P	P		P	P	P	Note1,2,4,6,7,10,14	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P	Note1,2,4,6,7	
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Cardiac	Intravascular								
Cardiac Adult										
Cardiac Pediatric										
Intravascular (Cardiac)										
Trans-esoph. (Cardiac)										
Peripheral vessel	Intra-cardiac									
	Peripheral vessel									
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System								
Transducer:	C11-3E								
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
Intravascular									
Cardiac	Cardiac Adult	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Cardiac Pediatric	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Other (Specify***)								
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E									
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.									
*Intraoperative includes abdominal, thoracic, and vascular									
**Small organ-breast, thyroid, testes.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.									
Note 2: Smart3D									
Note 3:4D(Real-time 3D)									
Note 4: iScape									
Note 5: TDI									
Note 6: Color M									
Note 7: Biopsy Guidance									
Note 8: Strain Elastography									
Note 9: Contrast imaging(contrast agent for LVO)									
Note 10: Contrast imaging (Contrast agent for Liver)									
Note 11: STE									
Note 12: STQ									
Note 13: Ultrasound Fusion Imaging									
Note 14: GYN/Pelvic									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of Device Evaluation(ODE)									

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	L14-6NE									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal	P	P	P		P	P	P	Note 1,2, 4,7	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P	Note 1,2, 4,7	
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,7,8	
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,7	
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2, 4,7	
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2, 4,7	
Intravascular										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2, 4,7	
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	L14-6WE									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal	P	P	P		P	P	P	Note 1,2, 4,7	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P	Note 1,2, 4,7	
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,7,8	
	Neonatal Cephalic	P	P	P		P	P	P	Note 1,2, 4,7	
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2, 4,7	
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2, 4,7	
	Intravascular									
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note 1,2, 4,7	
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	V11-3E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 4,6,7	
	Abdominal									
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal	P	P	P		P	P	P	Note 1, 2, 4,6,7,8	
	Trans-vaginal	P	P	P		P	P	P	Note 1, 2, 4,6,7,8,14	
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Intravascular										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel									
	Other (Specify***)	P	P	P		P	P	P	Note 1, 2, 4,6,7	
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	V11-3BE									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 2, 4,6,7	
	Abdominal									
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal	P	P	P		P	P	P	Note 1, 2, 4,6,7,8	
	Trans-vaginal	P	P	P		P	P	P	Note 1, 2, 4,6,7,8,14	
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Intravascular										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel									
	Other (Specify***)	P	P	P		P	P	P	Note 1, 2, 4,6,7	
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	DE10-3E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	P	P	P		P	P	P	Note 1, 3,4,6,7	
	Abdominal									
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal	P	P	P		P	P	P	Note 1, 3,4,6,7,8	
	Trans-vaginal	P	P	P		P	P	P	Note 1, 3,4,6,7,8,14	
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Cardiac	Intravascular									
	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
Peripheral vessel	Intra-cardiac									
	Peripheral vessel									
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	P4-2NE									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal	P	P	P	P	P	P	P	Note 1, 2,4,6,7	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P	P	P	P	P	Note 1, 2,4,6,7	
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2,4,6,7	
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Intravascular									
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7	
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1, 2,4,5,6,7	
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel									
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System										
Transducer:	P7-3E										
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:										
Clinical Application		Mode of Operation									
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)		
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal										
	Abdominal	P	P	P	P	P	P	P	Note 1, 2,4,6		
	Intra-operative (Specify*)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric	P	P	P	P	P	P	P	Note 1, 2,4,6		
	Small Organ (Specify**)										
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1, 2,4,6		
	Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2,4,6		
	Trans-rectal										
	Trans-vaginal										
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Conventional)	P	P	P	P	P	P	P	Note 1, 2,4,6		
	Musculo-skeletal (Superficial)										
Intravascular											
Cardiac	Cardiac Adult	P	P	P	P	P	P	P	Note 1, 2,4,5,6		
	Cardiac Pediatric	P	P	P	P	P	P	P	Note 1, 2,4,5,6		
	Intravascular (Cardiac)										
	Trans-esoph. (Cardiac)										
	Intra-cardiac										
Peripheral vessel	Peripheral vessel										
	Other (Specify***)										
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E											
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.											
*Intraoperative includes abdominal, thoracic, and vascular											
**Small organ-breast, thyroid, testes.											
***Other use includes Urology.											
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.											
Note 2: Smart3D											
Note 3:4D(Real-time 3D)											
Note 4: iScape											
Note 5: TDI											
Note 6: Color M											
Note 7: Biopsy Guidance											
Note 8: Strain Elastography											
Note 9: Contrast imaging(contrast agent for LVO)											
Note 10: Contrast imaging (Contrast agent for Liver)											
Note 11: STE											
Note 12: STQ											
Note 13: Ultrasound Fusion Imaging											
Note 14: GYN/Pelvic											
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)											
Concurrence of CDRH, Office of Device Evaluation(ODE)											

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	P10-4E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal	P	P	P	P	P	P	P	Note 1, 2,4,6	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P	P	P	P	P	Note 1, 2,4,6	
	Small Organ (Specify**)									
	Neonatal Cephalic	P	P	P	P	P	P	P	Note 1, 2,4,6	
	Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2,4,6	
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Cardiac	Intravascular								
Cardiac Adult		P	P	P	P	P	P	P	Note 1, 2,4,5,6	
Cardiac Pediatric		P	P	P	P	P	P	P	Note 1, 2,4,5,6	
Intravascular (Cardiac)										
Trans-esoph. (Cardiac)										
Peripheral vessel	Intra-cardiac									
	Peripheral vessel									
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	CB10-4E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal									
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal	P	P	P		P	P	P	Note 1, 2, 4,6,7	
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Intravascular										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel									
	Other (Specify***)	P	P	P		P	P	P	Note 1, 2, 4,6,7	
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	L16-4HE									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal	P	P	P		P	P	P	Note1,2,4	
	Intra-operative (Specify*)	P	P	P		P	P	P	Note1,2,4	
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	P	P	P		P	P	P	Note1,2,4	
	Small Organ (Specify**)	P	P	P		P	P	P	Note1,2,4	
	Neonatal Cephalic	P	P	P		P	P	P	Note1,2,4	
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note1,2,4	
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note1,2,4	
Intravascular										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel	P	P	P		P	P	P	Note1,2,4	
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	P7-3TE									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	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-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Cardiac	Intravascular								
Cardiac Adult										
Cardiac Pediatric										
Intravascular (Cardiac)										
Trans-esoph. (Cardiac)		P	P	P	P	P	P	P	Note 1, 5,6	
Peripheral vessel	Intra-cardiac									
	Peripheral vessel									
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	CW5s									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic Fetal Imaging & Other	Ophthalmic									
	Fetal									
	Abdominal									
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric				P					
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic				P					
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Intravascular									
Cardiac	Cardiac Adult				P					
	Cardiac Pediatric				P					
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel				N					
	Other (Specify***)									
N=new indication; P=previously cleared by FDA(K173471); E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	C5-2E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 2, 4,6,7	
	Abdominal	N	N	N		N	N	N	Note 1, 2, 4,6,7,14	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4,6,7	
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1, 2, 4,6,7	
	Cardiac	Musculo-skeletal (Superficial)								
Intravascular										
Cardiac Adult										
Cardiac Pediatric										
Intravascular (Cardiac)										
Peripheral vessel	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1, 2, 4,6,7	
	Other (Specify***)									
N=new indication; P=previously cleared by FDA; E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	P4-2E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal									
	Abdominal	N	N	N	N	N	N	N	Note 1,2,4,6,7	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N	N	N	N	N	Note 1,2,4,6,7	
	Small Organ (Specify**)									
	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1,2,4,6,7	
	Adult Cephalic	N	N	N	N	N	N	N	Note 1,2,4,6,7	
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Intravascular										
Cardiac	Cardiac Adult	N	N	N	N	N	N	N	Note 1,2,4,5,6,7	
	Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,2,4,5,6,7	
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel									
	Other (Specify***)									
N=new indication; P=previously cleared by FDA; E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	D6-2E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1,3,4,6,7	
	Abdominal	N	N	N		N	N	N	Note 1,3,4,6,7,14	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N		N	N	N	Note 1,3,4,6,7	
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
	Cardiac	Intravascular								
Cardiac Adult										
Cardiac Pediatric										
Intravascular (Cardiac)										
Trans-esoph. (Cardiac)										
Peripheral vessel	Intra-cardiac									
	Peripheral vessel									
	Other (Specify***)									
N=new indication; P=previously cleared by FDA; E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	SC6-1E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1,2,4,6,7,13	
	Abdominal	N	N	N		N	N	N	Note 1,2,4,6,7,10,11,12,13,14	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N		N	N	N	Note 1,2,4,6,7,13	
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,4,6,7,13	
	Musculo-skeletal (Superficial)									
Intravascular										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,4,6,7,13	
	Other (Specify***)									
N=new indication; P=previously cleared by FDA; E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System								
Transducer:	L20-5E								
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:								
Clinical Application		Mode of Operation							
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic								
Fetal Imaging & Other	Fetal								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2,4
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,4,8
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1,2,4,8
Cardiac	Intravascular								
	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
Peripheral vessel	Intra-cardiac								
	Peripheral vessel	N	N	N		N	N	N	Note 1,2,4
	Other (Specify***)								
N=new indication; P=previously cleared by FDA; E=added under Appendix E									
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.									
*Intraoperative includes abdominal, thoracic, and vascular									
**Small organ-breast, thyroid, testes.									
***Other use includes Urology.									
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.									
Note 2: Smart3D									
Note 3:4D(Real-time 3D)									
Note 4: iScape									
Note 5: TDI									
Note 6: Color M									
Note 7: Biopsy Guidance									
Note 8: Strain Elastography									
Note 9: Contrast imaging(contrast agent for LVO)									
Note 10: Contrast imaging (Contrast agent for Liver)									
Note 11: STE									
Note 12: STQ									
Note 13: Ultrasound Fusion Imaging									
Note 14: GYN/Pelvic									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of Device Evaluation(ODE)									

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	SD8-1E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 3, 4, 6,7	
	Abdominal	N	N	N		N	N	N	Note 1, 3, 4, 6,7,14	
	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-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Intravascular										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel									
	Other (Specify***)									
N=new indication; P=previously cleared by FDA; E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	DE10-3WE									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1, 3, 4, 6,7	
	Abdominal									
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal	N	N	N		N	N	N	Note 1, 3, 4, 6,7	
	Trans-vaginal	N	N	N		N	N	N	Note 1, 3, 4, 6,7,14	
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Intravascular										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel									
	Other (Specify***)									
N=new indication; P=previously cleared by FDA; E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System										
Transducer:	V11-3WE										
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:										
Clinical Application		Mode of Operation									
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)		
Ophthalmic	Ophthalmic										
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1,2,4,6,7		
	Abdominal										
	Intra-operative (Specify*)										
	Intra-operative (Neuro)										
	Laparoscopic										
	Pediatric										
	Small Organ (Specify**)										
	Neonatal Cephalic										
	Adult Cephalic										
	Trans-rectal	N	N	N		N	N	N	Note 1,2,4,6,7,8		
	Trans-vaginal	N	N	N		N	N	N	Note 1,2,4,6,7,8		
	Trans-urethral										
	Trans-esoph. (non-Card.)										
	Musculo-skeletal (Conventional)										
	Musculo-skeletal (Superficial)										
Intravascular											
Cardiac	Cardiac Adult										
	Cardiac Pediatric										
	Intravascular (Cardiac)										
	Trans-esoph. (Cardiac)										
	Intra-cardiac										
Peripheral vessel	Peripheral vessel										
	Other (Specify***)	N	N	N		N	N	N	Note 1,2,4,6,7		
N=new indication; P=previously cleared by FDA; E=added under Appendix E											
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.											
*Intraoperative includes abdominal, thoracic, and vascular											
**Small organ-breast, thyroid, testes.											
***Other use includes Urology.											
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.											
Note 2: Smart3D											
Note 3:4D(Real-time 3D)											
Note 4: iScape											
Note 5: TDI											
Note 6: Color M											
Note 7: Biopsy Guidance											
Note 8: Strain Elastography											
Note 9: Contrast imaging(contrast agent for LVO)											
Note 10: Contrast imaging (Contrast agent for Liver)											
Note 11: STE											
Note 12: STQ											
Note 13: Ultrasound Fusion Imaging											
Note 14: GYN/Pelvic											
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)											
Concurrence of CDRH, Office of Device Evaluation(ODE)											

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	SC5-1NE									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic	Ophthalmic									
Fetal Imaging & Other	Fetal	N	N	N		N	N	N	Note 1,2,4,6,7	
	Abdominal	N	N	N		N	N	N	Note 1,2,4,6,7,14	
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric	N	N	N		N	N	N	Note 1,2,4,6,7	
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal									
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)	N	N	N		N	N	N	Note 1,2,4,6,7	
	Musculo-skeletal (Superficial)									
Intravascular										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel	N	N	N		N	N	N	Note 1,2,4,6,7	
	Other (Specify***)									
N=new indication; P=previously cleared by FDA; E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

System:	DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System									
Transducer:	6LB7E									
Intended Use:	Diagnostic Ultrasound imaging or fluid flow analysis of the human body as follows:									
Clinical Application		Mode of Operation								
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)	
Ophthalmic Fetal Imaging & Other	Ophthalmic									
	Fetal									
	Abdominal									
	Intra-operative (Specify*)									
	Intra-operative (Neuro)									
	Laparoscopic									
	Pediatric									
	Small Organ (Specify**)									
	Neonatal Cephalic									
	Adult Cephalic									
	Trans-rectal	N	N	N		N	N	N	Note 1,2,4,6,7	
	Trans-vaginal									
	Trans-urethral									
	Trans-esoph. (non-Card.)									
	Musculo-skeletal (Conventional)									
	Musculo-skeletal (Superficial)									
Intravascular										
Cardiac	Cardiac Adult									
	Cardiac Pediatric									
	Intravascular (Cardiac)									
	Trans-esoph. (Cardiac)									
	Intra-cardiac									
Peripheral vessel	Peripheral vessel									
	Other (Specify***)	N	N	N		N	N	N	Note 1,2,4,6,7	
N=new indication; P=previously cleared by FDA; E=added under Appendix E										
Additional comments: Combined modes--B+M、PW+B、Color + B、Power + B、PW +Color+ B、Power + PW +B.										
*Intraoperative includes abdominal, thoracic, and vascular										
**Small organ-breast, thyroid, testes.										
***Other use includes Urology.										
Note 1: Tissue Harmonic Imaging. The feature does not use contrast agents.										
Note 2: Smart3D										
Note 3:4D(Real-time 3D)										
Note 4: iScape										
Note 5: TDI										
Note 6: Color M										
Note 7: Biopsy Guidance										
Note 8: Strain Elastography										
Note 9: Contrast imaging(contrast agent for LVO)										
Note 10: Contrast imaging (Contrast agent for Liver)										
Note 11: STE										
Note 12: STQ										
Note 13: Ultrasound Fusion Imaging										
Note 14: GYN/Pelvic										
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)										
Concurrence of CDRH, Office of Device Evaluation(ODE)										

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92(c).

The assigned 510(k) number is: K192152

1. Submitter:

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Date Prepared: July 25, 2019

2. Device Name: DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System

Classification

Regulatory Class: II

Review Category: Tier II

21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (IYN)

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer (ITX)

21 CFR 892.2050 Picture Archiving and Communications System(LLZ)

3. Device Description:

DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/

DC-TQ is a software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B-Mode, M-Mode, PW-Mode, CW-Mode, Color-Mode, Power/Dirpower Mode, THI, Smart3D, 4D, iScape, TDI, Color M, Biopsy Guidance, Strain Elastography, Contrast imaging (Contrast agent for Liver and LVO), STE, STQ, Ultrasound Fusion Imaging, GYN/Pelvic and the combined mode (i.e. B/M-Mode, B/PW-mode, B/PW/Color).

This system is a Track 3 device that employs an array of probes that include Linear array, Convex array, Phased array, Volume and Pencil probe.

4. Intended Use:

The DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, intra-operative (abdominal, thoracic, and vascular), pediatric, small organ (breast, thyroid, testes), neonatal and adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional, superficial), cardiac (adult, pediatric), trans-esoph. (Cardiac), peripheral vessel, and urology exams.

5. Summary of Modifications

- **New Added Transducers:**

C5-2E, P4-2E, D6-2E, SC6-1E, L20-5E, SD8-1E, DE10-3WE, V11-3WE, SC51-NE, 6LB7E;

- **New Added Needle-Guided Bracket:**

NGB-009, NGB-015, NGB-020, NGB-027, NGB-035, NGB-039;

- **Main Added Features:**

1. Ultrasound Fusion Imaging to C5-1E, SP5-1E, SC5-1E, L14-5WE, SC6-1E;
2. Smart Pelvic Floor to C5-1E, V11-3HE, D8-2E, D7-2E, DE11-3E, SC5-1E, D6-2NE, C6-2GE, V11-3E, V11-3BE, DE10-3E, C5-2E, D6-2E, SC6-1E, SD8-1E, DE10-3WE, SC5-1NE, C7-3E;
3. STE/STQ to L12-3E, L14-5WE, L9-3E, SC6-1E;

4. Strain Elastography to L20-5E, V11-3WE;
5. Add the peripheral vessel to the Clinical Application of CW5s ;;
6. Smart Face;
7. Smart Planes FH;
8. Glazing Flow;
9. Fusion RESP;
10. The DC-80 series has two hard disks (128G SSD+1T HDD);
11. The battery can provide power supply when scanning;
12. DC-80 series can support four or five transducer ports configuration;
13. The signal channel between the probe and the main host is 128.

6. Comparison with Predicate Devices:

DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/

DC-TQ Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1. Primary predicate device	Mindray	DC-70	K181637
2. Reference device	GE	Voluson E8	K181985
3. Reference device	Mindray	Resona 7	K171233
4. Reference device	Mindray	DC-90	K190206
5. Reference device	Mindray	DC-80	K173471
6. Reference device	Mindray	M9	K171034

DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/

DC-TQ has the same technological characteristics, is comparable in key safety and effectiveness features, and has the same intended uses and basic operating modes as the predicate devices. All systems transmit ultrasonic energy into patients and perform

post processing of received echoes to generate onscreen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

- Subject device

DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89

/DC-TV/DC-TQ has the samilar intended uses and transducer as the predicated device

DC-70 (K181637) ,DC-90 (K190206) , DC-80 (K173471) , M9 (K171034)

Subject Device DC-80	DC-70(predicate device)	DC-80(Reference device)	Resona 7(Reference device)	M9(Reference device)
C5-2E	C5-2E	/	/	/
P4-2E	P4-2E	/	/	/
L20-5E	L20-5E	/	/	/
6LB7E	6LB7E	/	/	/
SD8-1E	SD8-1E	/	/	/
SC5-1NE	C5-2E	/	/	/
D6-2E	/	D6-2NE	/	/
SC6-1E	/	C5-1E	/	/
DE10-3WE	/	/	DE10-3WU	/
V11-3WE	/	V11-3WE	/	/
CW5s	/	/	/	CW2s

DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/

DC-TQ has the same function as the predicated device Resona 7 (K171233)

Subject Device DC-80	Predicate device Resona7 (171233)
Ultrasound Fusion Imaging	Ultrasound Fusion Imaging
Smart Pelvic	Smart Pelvic
STE/STQ	STE/STQ
elastography	elastography
Smart Face	Smart Face

Smart Planes FH	Smart Planes FH
Fusion RESP	Fusion RESP

DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/
DC-TQ has the similar function as the Reference device Voluson™ E8 K181985

Subject Device DC-80	Predicate device(Voluson™ E8 K181985)
Glazing Flow	Glazing Flow

7. PERFORMANCE DATA

- Biocompatibility testing

The biocompatibility evaluation for the DC-80 device was conducted in accordance with International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

- Electrical safety and electromagnetic compatibility (EMC)

DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/
DC-TV/DC-TQ is Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the DC-80 Diagnostic
Ultrasound. The system complies with the IEC 60601-1, and IEC 60601-2-37
standards for safety and the IEC 60601-1-2 standard for EMC.

- DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/

DC-TV/DC-TQ is designed in compliance with the FDA recognized electrical and
physical safety standard, which is the same as the predicated device DC-70
(K181637), DC-90 (K190206) , DC-80 (K173471) , M9 (K171034)

- Acoustic Power Testing

The acoustic power levels of DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85
/DC-86/DC-86S/DC-89/DC-TV/DC-TQ are below the limits of FDA, as
recommended by FDA’s Guidance for Industry and FDA Staff “Marketing Clearance
of Diagnostic Ultrasound Systems and Transducers - Guidance for Industry and Food
and Drug Administration Staff”.

- Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

8. Non-clinical Tests:

DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been designed to conform with applicable medical safety standards. This device has been tested and evaluated under the following standards:

- AAMI/ANSI ES60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (Edition 3)
- IEC 60601-2-37: Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62304: Medical device software - Software life cycle processes
- IEC:62366:Medical devices - application of usability engineering to medical devices
- IEC 60601-1-6: medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability.
- ISO14971: Medical devices - Application of risk management to medical devices
- UD 2: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
- ISO 10993-1 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

These non-clinical tests relied on in this premarket notification submission can support the determination of substantial equivalence of the subject device.

9. Clinical Studies

Not applicable. The subject of this submission, DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

10. Summary

Based on the performance data as documented in the study, the DC-80 Diagnostic Ultrasound system was found to have a safety and effectiveness profile that is similar to the predicate device.

Conclusion:

Intended uses and other key features are consistent with traditional clinical practices, FDA guidelines and established methods of patient examination. The design, development and quality process of the manufacturer confirms with 21 CFR 820, ISO 9001 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards. Therefore, the DC-80/DC-80 PRO/DC-80 EXP/DC-80S/DC-85/DC-86/DC-86S/DC-89/DC-TV/DC-TQ Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.