



April 9, 2019

Shenzhen Mindray Bio-Medical Electronics Co., LTD
% Shi Jufang
Engineer of Technical Regulation
Keji 12th Road South, Hi-tech Industrial Park
Shenzhen, Guangdong, 518057
P.R. CHINA

Re: K183377

Trade/Device Name: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: Class II
Product Code: IYN, IYO, ITX
Dated: March 19, 2019
Received: March 21, 2019

Dear Shi Jufang:

This letter corrects our substantially equivalent letter of April 4, 2019.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

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

Sincerely,

A handwritten signature in black ink, appearing to read "David T. Mills", is positioned over a large, light blue, semi-transparent watermark of the letters "FDA".

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

Enclosure

Indications for Use

510(k) Number (if known)
K183377

Device Name
DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Indications for Use (Describe)

The DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional), musculo- skeletal (superficial), cardiac adult, cardiac pediatric, 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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Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: N/A

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
	Abdominal	P	P	P	P	P	P	P	Note 1, 2,3, 4,6,7, 9
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	P	N	P	P	P	Note 1, 2, 4,6,7
	Small Organ (Specify**)	P	P	P		P	P	P	Note 1,2, 4,6,7,8
	Neonatal Cephalic	P	P	P	N	P	P	P	Note 1, 2, 4,6,7
	Adult Cephalic	P	P	P	P	P	P	P	Note 1, 2,4,6,7
	Trans-rectal	P	P	P		P	P	P	Note 1, 2, 3,4,6,7
	Trans-vaginal	P	P	P		P	P	P	Note 1, 2, 3,4,6,7
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1, 2, 4,6,7,8
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2, 4,6,7,8
Cardiac	Intravascular								
	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)								
Peripheral vessel	Intra-cardiac								
	Peripheral vessel	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Other (Specify***)	N	N	N		N	N	N	Note 1, 2, 4,6,7
N=new indication; P=previously cleared by FDA (K162845); 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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: 3C5A

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	P	P	P		P	P	P	Note 1, 2, 4,6,7,9
	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)	P	P	P		P	P	P	Note 1, 2, 4,6,7
	Musculo-skeletal (Superficial)								
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, 4,6,7
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (k162845); 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.									
*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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: 7L4A

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**)	P	P	P		P	P	P	Note 1,2, 4,6,7,8
	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)	P	P	P		P	P	P	Note 1,2, 4,6,7,8
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2, 4,6,7,8
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 (k162845); 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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: L7-3

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**)	P	P	P		P	P	P	Note 1,2, 4,6,7
	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)	P	P	P		P	P	P	Note 1,2, 4,6,7
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2, 4,6,7
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, 4,6,7
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (k162845); E=added under Appendix E									
Additional comments: Combined modes--B+M, PW+B, Color + B, Power + B, PW +Color+ B, Power + PW +B.									
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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro 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
	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)								
Peripheral vessel	Intra-cardiac								
	Peripheral vessel								
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (k162845); 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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro 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								
	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								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	P		P	P	P	Note 1,2, 4,7,8
	Musculo-skeletal (Superficial)	P	P	P		P	P	P	Note 1,2, 4,7,8
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 (k162845); 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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: V11-3

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
	Trans-vaginal	P	P	P		P	P	P	Note 1, 2, 4,6,7
	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 (k162845); 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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: P4-2

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								
	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 (k162845); 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									
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Note 4: iScape									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro 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	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 (k162845); 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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro 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	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
	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 (k162845); 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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: 6LB7

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	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 (k162845); 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

Note5: TDI

Note6: Color M

Note7: Biopsy Guidance

Note8: Elastography

Note9: Contrast imaging (Contrast agent for Liver)

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

Prescription USE (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: L13-3

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	Note 1, 2, 4,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4,7
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1,2, 4,7, 8
	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, 4,7,8
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4,7,8
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, 4,7
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (k162845); 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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: 7L4B

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	Note 1, 2, 4,7
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N		N	N	N	Note 1, 2, 4,7
	Small Organ (Specify**)	N	N	N		N	N	N	Note 1, 2, 4,7,8
	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, 4,7,8
	Musculo-skeletal (Superficial)	N	N	N		N	N	N	Note 1, 2, 4,7,8
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, 4,7
	Other (Specify***)								
N=new indication; P=previously cleared by FDA (k162845); 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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: C6-2

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

Clinical Application		Mode of Operation							
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, 4,6,7,9
	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	N	N	N		N	N	N	Note 1, 2, 4,6,7
	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 (k162845); 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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System

Transducer: D7-2

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
	Abdominal	N	N	N		N	N	N	Note 1, 3, 4, 6
	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 (k162845); 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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

Diagnostic Ultrasound Indications For Use Format

System: DC-40/DC-35/DC-45/DC-40S/DC-40 Pro 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	N	N	N	N	N	N	N	Note 1, 2,4,6
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	N	N	N	N	N	N	N	Note 1, 2,4,6
	Small Organ (Specify**)								
	Neonatal Cephalic	N	N	N	N	N	N	N	Note 1, 2,4,6
	Adult Cephalic	N	N	N	N	N	N	N	Note 1, 2,4,6
	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
	Cardiac Pediatric	N	N	N	N	N	N	N	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 (k162845); 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									
Note5: TDI									
Note6: Color M									
Note7: Biopsy Guidance									
Note8: Elastography									
Note9: Contrast imaging (Contrast agent for Liver)									
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE NEEDED)									
Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									
Prescription USE (Per 21 CFR 801.109)									

K183377

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).

1. Submitter:

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Date Prepared: November 28, 2018

2. Device Name:

DC-40/DC-35/DC-45/DC-40S/DC-40 Pro 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)

3. Device Description:

The DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System is a general purpose, mobile, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound images in B-Mode, M-Mode, PW-Mode, CW-mode, Color-Mode, Power/Dirpower mode, THI Mode, 3D/4D Mode, iScape mode, TDI mode, Color M mode, Biospy Guidance, Elastography, Contrast imaging (Liver) or 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, Phased array and convex array.

4. Intended Use:

The DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ (breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal, musculo-skeletal (conventional), musculo- skeletal(superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.

5. Summary of Modifications and New Added Features

This submission device is a modifications to DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System previously cleared in K162845.

The following is a brief overview of the modifications and new added features:

- **New added transducers**
DE11-3E, 6LB7, L13-3, 7L4B, C6-2, D7-2, CB10-4E, P10-4E
- **New added needle-guided brackets**
NGB-009, NGB-022, NGB-027
- **New added features**
Add Contrast imaging (contrast agent for Liver)
Add the musculo-skeletal elastography function to transducers 7L4A、 L14-6NE
Smart Volume
Smart FLC
Smart Face
Face+ (subfunction of Smart Face)
optional DVD recorder
- **The other changes**
Change the size of LCD monitor
Increase the MP4 format in the exported format list

6. Comparison with Predicate Devices:

The modified DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Number
1. Primary predicate	Mindray	DC-40	K162845

device			
2. Reference device	Mindray	M6	K171579
3. Reference device	Mindray	DC-7	K103583
4. Reference device	Mindray	Resona 7	K171233
5. Reference device	Mindray	DC-70	K163690
6. Reference device	Mindray	Z6	K122010

The modified DC-40/DC-35/DC-45/DC-40S/DC-40 Pro Diagnostic Ultrasound System employs the same technology as the predicate devices. All systems transmit ultrasonic energy into patients, then 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. The subject device also has the same intended uses and basic operating modes as the predicate devices.

- Subject device DC-40/DC-35/DC-45/DC- 40S/DC- 40 Pro has the same intended uses as the predicated device DC-40 (K162845).

Items	Subject Device DC-40/DC-35/DC-45/DC-40 S/DC-40 Pro	Predicate device DC-40(K162845)
Intended Use	The DC-40/DC-35/DC-45/DC-40S/DC- 40 Pro Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal,	The DC-40/DC-35/DC-45/DC-40S/DC- 40 Pro Diagnostic Ultrasound System is applicable for adults, pregnant women, pediatric patients and neonates. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes), neonatal cephalic, adult cephalic, trans-rectal, trans-vaginal,

	musculo-skeletal (conventional), musculo- skeletal(superficial), cardiac adult, cardiac pediatric, peripheral vessel and urology exams.	musculo-skeletal (conventional), musculo- skeletal(superficial), cardiac adult, cardiac pediatric and peripheral vessel exams.
		urology exam M6 (K171579)

- The patient contact materials of the new added transducers and needle-guided brackets are tested under ISO 10993-1.
- The acoustic power levels of modified DC-40/DC-35/DC-45/DC- 40S/DC- 40 Pro are below the limits of FDA, which are the same as the predicated device DC-40 (K162845).
- The modified DC-40/DC-35/DC-45/DC- 40S/DC- 40 Pro is designed in compliance with the FDA recognized electrical and physical safety standards, which are the same as the predicated device DC-40 (K162845).
- The modified DC-40/DC-35/DC-45/DC- 40S/DC- 40 Pro has the same imaging modes as the predicated devices.
- The new added features of modified DC-40/DC-35/DC-45/DC- 40S/DC- 40 Pro are the same as the predicate devices.
- The modified DC-40/DC-35/DC-45/DC- 40S/DC- 40 Pro has similar transducers with the predicate devices.

7. Non-clinical Tests:

DC-40/DC-35/DC-45/DC- 40S/DC- 40 Pro 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 found to conform with applicable medical safety standards.

Non-clinical tests relied on in this premarket notification submission for a determination of substantial equivalence include testing showing compliance with the following standards:

- ANSI/AAMI ES60601-1 :2005/(R)2012 and A1:2012: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Edition 4.0 2014-02: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests

- IEC 60601-2-37 Edition 2.1 2015: Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
- IEC 62304 Edition 1.1 2015-06: Medical device software - Software life cycle processes
- IEC 62366-1 Edition 1.0 2015-02: Medical devices - application of usability engineering to medical devices
- IEC 60601-1-6 Edition 3.1 2013-10: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
- ISO 14971 Second edition 2007-03-01: Medical devices - Application of risk management to medical devices
- NEMA UD 2-2004 (R2009): Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Revision 3
- ISO 10993-1 Fourth edition 2009-10-15: Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process, Fourth edition
These non-clinical tests relied on in this premarket notification submission can support the determination of substantial equivalence of the subject device.

8. Clinical Tests:

Not applicable. The subject of this submission, DC-40/DC-35/DC-45/DC- 40S/DC- 40 Pro Diagnostic Ultrasound System, does not require clinical studies to support substantial equivalence.

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-40/DC-35/DC-45/DC- 40S/DC- 40 Pro Diagnostic Ultrasound System is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.