DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*

K183660

Device Name
DP-10/DP-20/DP-30 Digital Ultrasonic Diagnostic Imaging System

Indications for Use *(Describe)*

DP-10/DP-20/DP-30 Digital Ultrasonic Diagnostic Imaging 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, superficial), cardiac (adult, pediatric), peripheral vascular 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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Resp-013-1

Diagnostic Ultrasound Indications For Use Format

System: DP-10/DP-20 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	N				P	Note1, Note 2
	Abdominal	P	P	N				P	Note1, Note 2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N				P	Note1, Note 2
	Small Organ (Specify**)	P	P	N				P	Note 2
	Neonatal Cephalic	P	P	N				P	Note 2
	Adult Cephalic	P	P	N				P	Note 2
	Trans-rectal	P	P	N				P	Note 2
	Trans-vaginal	P	P	N				P	Note 2
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N				P	Note1, Note 2
	Musculo-skeletal (Superficial)	P	P	N				P	Note 2
	Intravascular								
Cardiac	Cardiac Adult	P	P	N				P	Note 2
	Cardiac Pediatric	P	P	N				P	Note 2
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	N				P	Note 2
	Other (Specify***)	P	P	N				P	Note1, Note 2
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, 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: Biopsy Guidance									
(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)

35C20EA

System: DP-10/DP-20 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								
	Abdominal	P	P	N				P	Note 2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N				P	Note 2
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N				P	Note 2
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult	P	P	N				P	Note 2
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	N				P	Note 2
	Other (Specify***)								
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, 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: Biopsy Guidance									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

Prescription USE (Per 21 CFR 801.109)

35C50EB

System: DP-10/DP-20 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	N				P	Note1, Note 2
	Abdominal	P	P	N				P	Note1, Note 2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N				P	Note1, Note 2
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N				P	Note1, Note 2
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vascular	Peripheral Vascular								
	Other (Specify***)	P	P	N				P	Note1, Note 2
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, 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: Biopsy Guidance									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

Prescription USE (Per 21 CFR 801.109)

65C15EA

System: DP-10/DP-20 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								
	Abdominal	P	P	N				P	Note 2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N				P	Note 2
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	N				P	Note 2
	Adult Cephalic	P	P	N				P	Note 2
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N				P	Note 2
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	N				P	Note 2
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	N				P	Note 2
	Other (Specify***)								
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, 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: Biopsy Guidance									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

Prescription USE (Per 21 CFR 801.109)

65EC10EB

System: DP-10/DP-20 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	N				P	Note 2
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	N				P	Note 2
	Adult Cephalic								
	Trans-rectal	P	P	N				P	Note 2
	Trans-vaginal	P	P	N				P	Note 2
	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 Vascular	Peripheral Vascular								
	Other (Specify***)	P	P	N				P	Note 2
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, 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: Biopsy Guidance									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

Prescription USE (Per 21 CFR 801.109)

75L38EB

System: DP-10/DP-20 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								
	Abdominal	P	P	N				P	Note 2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N				P	Note 2
	Small Organ (Specify**)	P	P	N				P	Note 2
	Neonatal Cephalic	P	P	N				P	Note 2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N				P	Note 2
	Musculo-skeletal (Superficial)	P	P	N				P	Note 2
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	N				P	Note 2
	Other (Specify***)								
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, 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: Biopsy Guidance									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

Prescription USE (Per 21 CFR 801.109)

75L53EA

System: DP-10/DP-20 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								
	Abdominal	P	P	N				P	Note 2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N				P	Note 2
	Small Organ (Specify**)	P	P	N				P	Note 2
	Neonatal Cephalic	P	P	N				P	Note 2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N				P	Note 2
	Musculo-skeletal (Superficial)	P	P	N				P	Note 2
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	N				P	Note 2
	Other (Specify***)								
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, 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: Biopsy Guidance									
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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: DP-30 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	N			N	P	Note1, Note 2
	Abdominal	P	P	N			N	P	Note1, Note 2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N			N	P	Note1, Note 2
	Small Organ (Specify**)	P	P	N			N	P	Note 2
	Neonatal Cephalic	P	P	N			N	P	Note 2
	Adult Cephalic	P	P	N			N	P	Note 2
	Trans-rectal	P	P	N			N	P	Note 2
	Trans-vaginal	P	P	N			N	P	Note 2
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N			N	P	Note1, Note 2
	Musculo-skeletal (Superficial)	P	P	N			N	P	Note 2
	Intravascular								
Cardiac	Cardiac Adult	P	P	N			N	P	Note 2
	Cardiac Pediatric	P	P	N			N	P	Note 2
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	N			N	P	Note 2
	Other (Specify***)	P	P	N			N	P	Note1, Note 2
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, PW+B, Power + 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: Biopsy Guidance									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

Prescription USE (Per 21 CFR 801.109)

35C20EA

System: DP-30 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								
	Abdominal	P	P	N			N	P	Note 2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N			N	P	Note 2
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N			N	P	Note 2
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult	P	P	N			N	P	Note 2
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	N			N	P	Note 2
	Other (Specify***)								
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, PW+B, Power + 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: Biopsy Guidance									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

Prescription USE (Per 21 CFR 801.109)

35C50EA

System: DP-30 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	N			N	P	Note1, Note 2
	Abdominal	P	P	N			N	P	Note1, Note 2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N			N	P	Note1, Note 2
	Small Organ (Specify**)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N			N	P	Note1, Note 2
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vascular	Peripheral Vascular								
	Other (Specify***)	P	P	N			N	P	Note1, Note 2
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, PW+B, Power + 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: Biopsy Guidance									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

Prescription USE (Per 21 CFR 801.109)

65C15EA

System: DP-30 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								
	Abdominal	P	P	N			N	P	Note 2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N			N	P	Note 2
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	N			N	P	Note 2
	Adult Cephalic	P	P	N			N	P	Note 2
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N			N	P	Note 2
	Musculo-skeletal (Superficial)								
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P	N			N	P	Note 2
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	N			N	P	Note 2
	Other (Specify***)								
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, PW+B, Power + 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: Biopsy Guidance									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

Prescription USE (Per 21 CFR 801.109)

65EC10EA

System: DP-30 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	N			N	P	Note 2
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)								
	Neonatal Cephalic	P	P	N			N	P	Note 2
	Adult Cephalic								
	Trans-rectal	P	P	N			N	P	Note 2
	Trans-vaginal	P	P	N			N	P	Note 2
	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 Vascular	Peripheral Vascular								
	Other (Specify***)	P	P	N			N	P	Note 2
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, PW+B, Power + 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: Biopsy Guidance									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

Prescription USE (Per 21 CFR 801.109)

75L38EA

System: DP-30 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								
	Abdominal	P	P	N			N	P	Note 2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N			N	P	Note 2
	Small Organ (Specify**)	P	P	N			N	P	Note 2
	Neonatal Cephalic	P	P	N			N	P	Note 2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N			N	P	Note 2
	Musculo-skeletal (Superficial)	P	P	N			N	P	Note 2
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	N			N	P	Note 2
	Other (Specify***)								
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, PW+B, Power + 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: Biopsy Guidance									
(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)

75L53EA

System: DP-30 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								
	Abdominal	P	P	N			N	P	Note 2
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric	P	P	N			N	P	Note 2
	Small Organ (Specify**)	P	P	N			N	P	Note 2
	Neonatal Cephalic	P	P	N			N	P	Note 2
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N			N	P	Note 2
	Musculo-skeletal (Superficial)	P	P	N			N	P	Note 2
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	N			N	P	Note 2
	Other (Specify***)								
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, PW+B, Power + 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: Biopsy Guidance									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

Prescription USE (Per 21 CFR 801.109)

10L24EA

System: DP-30 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								
	Abdominal								
	Intra-operative (Specify*)								
	Intra-operative (Neuro)								
	Laparoscopic								
	Pediatric								
	Small Organ (Specify**)	P	P	N			N	P	Note 2
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph. (non-Card.)								
	Musculo-skeletal (Conventional)	P	P	N			N	P	Note 2
	Musculo-skeletal (Superficial)	P	P	N			N	P	Note 2
	Intravascular								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular (Cardiac)								
	Trans-esoph. (Cardiac)								
	Intra-cardiac								
Peripheral Vascular	Peripheral Vascular	P	P	N			N	P	Note 2
	Other (Specify***)								
N=new indication；P=previously cleared by FDA； E=added under Appendix E									
Additional comments：Combined modes--B+M, PW+B, Power + 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: Biopsy Guidance									
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Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)									

Prescription USE (Per 21 CFR 801.109)