

Indications for Use

510(k) Number (if known)

K163121

Device Name

SmartUs EXT-1M/3M

Indications for Use (Describe)

SmartUs EXT-1M/3M ultrasound imaging system is intended to be used for applications in fetal, abdominal, pediatric, small organ (breast, thyroid, testicles), adult cephalic, musculo-skeletal (conventional), musculo-skeletal (superficial), cardiac adult, cardiac pediatric, peripheral vessel (B and M-mode, combined modes imaging, including imaging for needle guidance). It is possible to provide diagnostic information outside of an imaging lab, including at the bedside systems, for navigated medical application, in operating rooms/critical care units.

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.

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

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Diagnostic Ultrasound Indications for Use Form**System:** SmartUs EXT-1M/3M**Intended Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**Table 1.3-1**

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Note 1	Note 2,3,4
	Abdominal	N	N	N		N	Note 1	Note 2,3,4
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2,3,4
	Small Organ (specify)	N	N	N		N	Note 1	Note 2,3,4
	Neonatal Cephalic							
	Adult Cephalic	N	N	N		N	Note 1	Note 4
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal (Conventional)	N	N	N		N	Note 1	Note 2,3,4
	Musculo-skeletal (Superficial)	N	N	N		N	Note 1	Note 2,3,4
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult	N	N	N		N	Note 1	Note 2,3,4
	Cardiac Pediatric	N	N	N		N	Note 1	Note 4
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 2,3,4
	Other (specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note 1 - Combined Modes: M(B+M), B(B+M), B+M, B(B+PW), PW(B+PW), B+PW, B(B+CFM/PDI/DPDI), CFM/PDI/DPDI (B+CFM/PDI/DPDI), B+CFM/PDI/DPDI, B(B+CFM/PDI/DPDI+PW), CFM/PDI/DPDI (B+CFM/PDI/DPDI+PW), PW(B+CFM/PDI/DPDI+PW), B+CFM/PDI/DPDI+PW,

Note 2 - Includes Imaging for Needle Guidance

Note 3 - Small Organs (specifically Breast, Thyroid, Testicles)

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance

Diagnostic Ultrasound Indications for Use Form**System:** SmartUs EXT-1M/3M**Transducer:** Convex array C5-2R60HI-5**Intended Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**Table 1.3-2**

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal	N	N	N		N	Note 1	Note 2,3,4
	Abdominal	N	N	N		N	Note 1	Note 2,3,4
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify) ¹							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
	Intravascular							
Other (specify)								
Cardiac	Cardiac Adult	N	N	N		N	Note 1	Note 2,3,4
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel							
	Other (specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note 1 - Combined Modes: M(B+M), B(B+M), B+M, B(B+PW), PW(B+PW), B+PW, B(B+CFM/PDI/DPDI), CFM/PDI/DPDI (B+CFM/PDI/DPDI), B+CFM/PDI/DPDI, B(B+CFM/PDI/DPDI+PW), CFM/PDI/DPDI (B+CFM/PDI/DPDI+PW), PW(B+CFM/PDI/DPDI+PW), B+CFM/PDI/DPDI+PW,

Note 2 - Includes Imaging for Needle Guidance

Note 3 - Small Organs (specifically Breast, Thyroid, Testicles)

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance

Note 4 - Tissue harmonic Imaging (THI)

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Diagnostic Ultrasound Indications for Use Form**System:** SmartUs EXT-1M/3M**Transducer:** Linear array L15-7L40HI-5**Intended Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**Table 1.3-3**

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric	N	N	N		N	Note 1	Note 2,3,4
	Small Organ (specify)	N	N	N		N	Note 1	Note 2,3,4
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal (Conventional)	N	N	N		N	Note 1	Note 2,3,4
	Musculo-skeletal (Superficial)	N	N	N		N	Note 1	Note 2,3,4
	Intravascular							
	Other (specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel	N	N	N		N	Note 1	Note 2,3,4
	Other (specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note 1 - Combined Modes: M(B+M), B(B+M), B+M, B(B+PW), PW(B+PW), B+PW, B(B+CFM/PDI/DPDI), CFM/PDI/DPDI (B+CFM/PDI/DPDI), B+CFM/PDI/DPDI, B(B+CFM/PDI/DPDI+PW), CFM/PDI/DPDI (B+CFM/PDI/DPDI+PW), PW(B+CFM/PDI/DPDI+PW), B+CFM/PDI/DPDI+PW,

Note 2 - Includes Imaging for Needle Guidance

Note 3 - Small Organs (specifically Breast, Thyroid, Testicles)

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance

Diagnostic Ultrasound Indications for Use Form**System:** SmartUs EXT-1M/3M**Transducer:** Phased array P5-1L15SI-6**Intended Use:** Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:**Table 1.3-4**

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Track 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (specify)	Other (specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal	N	N	N		N	Note 1	Note 4
	Intraoperative (specify)							
	Intraoperative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (specify)							
	Neonatal Cephalic							
	Adult Cephalic	N	N	N		N	Note 1	Note 4
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (Non-Card)							
	Musculo-skeletal (Conventional)							
	Musculo-skeletal (Superficial)							
Intravascular								
Other (specify)								
Cardiac	Cardiac Adult	N	N	N		N	Note 1	Note 4
	Cardiac Pediatric	N	N	N		N	Note 1	Note 4
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (specify)							
Peripheral Vessel	Peripheral vessel							
	Other (specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Note 1 - Combined Modes: M(B+M), B(B+M), B+M, B(B+PW), PW(B+PW), B+PW, B(B+CFM/PDI/DPDI), CFM/PDI/DPDI (B+CFM/PDI/DPDI), B+CFM/PDI/DPDI, B(B+CFM/PDI/DPDI+PW), CFM/PDI/DPDI (B+CFM/PDI/DPDI+PW), PW(B+CFM/PDI/DPDI+PW), B+CFM/PDI/DPDI+PW,

Note 2 - Includes Imaging for Needle Guidance

Note 3 - Small Organs (specifically Breast, Thyroid, Testicles)

Note 4 - Tissue harmonic Imaging (THI)

Note 5 - Intraoperative applications: Include Needle Guidance