K123503

510(K) SUMMARY

DEC 1 3 2012

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: _____.

1. Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

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Contact Person:
Bai Yanhong
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

Date Prepared: September 7, 2012

2. Device Name: DC-N3/DC-N3S Diagnostic Ultrasound System

Classification
Regulatory Class: II
Review Category: Tier II
21 CFR 892.1550 Ultrasonic Pulsed Doppler Imaging System (90-IYN)
21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System (90-IYO)
21 CFR 892.1570 Diagnostic Ultrasound Transducer (90-ITX)

3. Device Description:

DC-N3/DC-N3S is a mobile, software controlled, ultrasonic diagnostic system. Its function is to acquire and display ultrasound data in B, M, PW, CW, Color, Power, HPRF, TVI, TEI,TVD, Free Xros M/ Free Xros CM, Smart 3D, 4D, iScape, 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, convex array and phased

array with a frequency range of approximately 2.5 MHz to 10.0 MHz.

4. Intended Use:

DC-N3/DC-N3S Diagnostic Ultrasound System is applicable for adult, pregnant woman, pediatric and neonate. It is intended for use in fetal, abdominal, pediatric, small organ(breast, thyroid, testes.), cephalic(neonatal and adult), trans-rectal, trans-vaginal, musculo-skeletal(conventional, superficial), cardiac(Adult and Pediatric), Peripheral Vascular and urology exams.

5. Comparison with Predicate Devices:

DC-N3/DC-N3S Diagnostic Ultrasound System is comparable with and substantially equivalent to these predicate devices:

Predicate Device	Manufacturer	Model	510(k) Control Number
1 [redacted]	Mindray	DC-7	K103583
2 [redacted]	Mindray	DC-T6	K120699
3 [redacted]	Mindray	DC-8	K113647
4 [redacted]	Mindray	Z6	K122010

They have the same technological characteristics, are comparable in key safety and effectiveness features, and have the same intended uses and basic operating modes as the predicate devices.

6. Non-clinical Tests:

DC-N3/DC-N3S 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. This device has been designed to meet the following standards: UD 2, UD 3, IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37,UL 60601-1, ISO14971 and ISO 10993-1.

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-N3/DC-N3S Diagnostic Ultrasound System is

substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 13, 2012

Shenzhen Mindray Bio-Medical Electronics., Ltd.
% Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K123503
Trade/Device Name: The DC-N3/DC-N3S Diagnostic Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: October 31, 2012
Received: November 13, 2012

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the The DC-N3/DC-N3S Diagnostic Ultrasound System as described in your premarket notification:

Transducer Model Number

3C5A	L14-6
6C2	2P2
V10-4	D6-2
V10-4B	D6-2A
7L4A	6CV1
L12-4	

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device

can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (301) 796-6881.

Sincerely Yours,

Janine M. Morris -S

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known):

Device Name: The DC-N3/ DC-N3S Diagnostic Ultrasound System

Indications for Use:

The DC-N3/ DC-N3S 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), cephalic (neonatal and adult), trans-rectal, trans-vaginal, musculo-skeletal (conventional and superficial), cardiac (adult and pediatric), peripheral vascular and urology exams.

Prescription Use__X__ AND/OR Over – The – Counter Use___

(21 CFR Part 801 Subpart D) (21 CFR Part 807 Subpart C)

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

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123503

Diagnostic Ultrasound Indications for Use Form

System X Transducer _____

Model: DC-N3

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Note1,2, 3, 4,6,7
Abdominal	N	N	N	N	N	N	N	Note1,2, 3, 4,5,6,7
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N	N	N	N	N	Note 1, 2, 4,5,6,7
Small organ(specify)**	N	N	N		N	N	N	Note1, 2, 4,6,7
Neonatal Cephalic	N	N	N	N	N	N	N	Note1, 2, 4,5,6,7
Adult Cephalic	N	N	N	N	N	N	N	Note1, 2, 4,5,6,7
Trans-rectal	N	N	N		N	N	N	Note 1,2,4,6,7
Trans-vaginal	N	N	N		N	N	N	Note 1,2,4,6,7
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal	N	N	N		N	N	N	Note 1,2,4,6,7
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2,4,6,7
Intravascular								
Cardiac Adult	N	N	N	N	N	N	N	Note 1,2,5,6,7
Cardiac Pediatric	N	N	N	N	N	N	N	Note 1,2,5,6,7
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	N	N	N		N	N	N	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; 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 etc.

**Small organ-breast, thyroid, testes, etc.

***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

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123503

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: 3C5A

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
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
Intraoperative (specify)*								
Intraoperative (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	N	N	N		N	N	N	Note 1, 2, 4,6,7
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	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 etc.

**Small organ-breast, thyroid, testes, etc.

***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

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123503

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: 6C2

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N		N	N	N	Note 1, 2, 4,6,7
Intraoperative (specify)*								
Intraoperative (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	N	N	N		N	N	N	Note 1, 2, 4,6,7
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal	N	N	N		N	N	N	Note 1, 2, 4,6,7
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1, 2, 4,6,7
Intravascular								
Cardiac Adult	N	N	N		N	N	N	Note 1, 2, 4,6,7
Cardiac Pediatric	N	N	N		N	N	N	Note 1, 2, 4,6,7
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	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 etc.

**Small organ-breast, thyroid, testes, etc.

***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

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123503

08-4

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: V10-4

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Note 1, 2, 4,6,7
Abdominal								
Intraoperative (specify)*								
Intraoperative (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	N	N	N		N	N	N	Note 1, 2, 4,6,7
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
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 etc.

**Small organ-breast, thyroid, testes, etc.

***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

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123503

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: V10-4B

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Pote 1, 2, 4,6,7
Abdominal								
Intraoperative (specify)*								
Intraoperative (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	N	N	N		N	N	N	Note 1, 2, 4,6,7
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
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 etc.

**Small organ-breast, thyroid, testes, etc.

***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

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123503

08-6

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 7L4A

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N		N	N	N	Note 1,2, 4,6,7
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1,2, 4,6,7
Small organ(specify)**	N	N	N		N	N	N	Note 1,2, 4,6,7
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	N	N	N		N	N	N	Note 1,2, 4,6,7
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2, 4,6,7
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	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 etc.

**Small organ-breast, thyroid, testes, etc.

***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

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123503

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: L12-4

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N		N	N	N	Note 1,2, 4,6,7
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1,2, 4,6,7
Small organ(specify)**	N	N	N		N	N	N	Note 1,2, 4,6,7
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	N	N	N		N	N	N	Note 1,2, 4,6,7
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2, 4,6,7
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	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 etc.

**Small organ-breast, thyroid, testes, etc.

***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

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123503

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: L14-6

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N		N	N	N	Note 1,2, 4,6,7
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N		N	N	N	Note 1,2, 4,6,7
Small organ(specify)**	N	N	N		N	N	N	Note 1,2, 4,6,7
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	N	N	N		N	N	N	Note 1,2, 4,6,7
Musculo-skeletal Superficial	N	N	N		N	N	N	Note 1,2, 4,6,7
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular	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 etc.

**Small organ-breast, thyroid, testes, etc.

***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

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

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

(Division Sign Off)

Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123503

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: 2P2

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal								
Abdominal	N	N	N	N	N	N	N	Note 1, 2,4,5,6,7
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric	N	N	N	N	N	N	N	Note 1, 2,4,5,6,7
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, 2,4,5,6,7
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal								
Musculo-skeletal Superficial								
Intravascular								
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 Vascular								
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 etc.

**Small organ-breast, thyroid, testes, etc.

***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

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Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription USE (Per 21 CFR 801.109)

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Division of Radiological Health

Office of In Vitro Diagnostics and Radiological Health

510(k) K123503

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: D6-2

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Note1,2, 3, 4,6
Abdominal	N	N	N		N	N	N	Note1,2, 3, 4,6
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
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 etc.

**Small organ-breast, thyroid, testes, etc.

***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

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123503

08-11

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer X

Model: D6-2A

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Note1,2, 3, 4,6
Abdominal	N	N	N		N	N	N	Note1,2, 3, 4,6
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal								
Trans-vaginal								
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
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 etc.

**Small organ-breast, thyroid, testes, etc.

***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

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510(k) K123503

Diagnostic Ultrasound Indications for Use Form

System _____ Transducer ×

Model: 6CV1

510(k) Number(s) _____

Clinical Application	Mode of Operation							
	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined (specify)	Other (specify)
Ophthalmic								
Fetal	N	N	N		N	N	N	Note1,2, 4,6,7
Abdominal								
Intraoperative (specify)*								
Intraoperative (Neuro)								
Laparoscopic								
Pediatric								
Small organ(specify)**								
Neonatal Cephalic								
Adult Cephalic								
Trans-rectal	N	N	N		N	N	N	Note1,2, 4,6,7
Trans-vaginal	N	N	N		N	N	N	Note1,2, 4,6,7
Trans-urethral								
Trans-esoph.(non-Card.)								
Musculo-skeletal								
Musculo-skeletal Superficial								
Intravascular								
Cardiac Adult								
Cardiac Pediatric								
Intravascular (Cardiac)								
Trans-esoph.(Cardiac)								
Intra-Cardiac								
Peripheral Vascular								
Other (specify)***	N	N	N		N	N	N	Note1,2, 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 etc.

**Small organ-breast, thyroid, testes, etc.

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