K082480

Section III 510(k) Summary

FEB 25 2009

As Required by CFR 807.92

Sponsor:	Contec Medical Systems Co., LTD No.2-1 Hengshan Road, Economic and Technical Development Zone Qinhuangdao, Hebei, 066000, People's Republic of China Mr. Li Xueyong Quality Manager Tel: Fax: Email:
Correspondent:	Shanghai Mid-Link Business Consulting Co., Ltd Suite 8D, No.19, Lane 999, Zhongshan No.2 Road(S) Shanghai, 200030, China Ms. Diana Hong / Mr. Lee Fu Tel: 021-64264467 Fax: (760)466-5084 Email: diana.hong@mid-link.net
Proposed Device:	**Device Trade/Proprietary Name:** Contec Pocket Fetal Doppler **Model:** SONOLINE A/ SONOLINE B/Baby Sound A/Baby Sound B **Device Common Name:** Fetal ultrasonic monitor and accessories **Device Classification Name:** monitor, ultrasonic, fetal **Product Code:** KNG **Regulation Number:** 884.2660 **Device Class:** II

Intended Use:	Contect Pocket Fetal Doppler (SONOLINE A, SONOLINE B, Baby Sound A and Baby Sound B) are hand-held, battery powered audio Doppler devices used for detecting fetal heart beats. They are all available for user replaceable batteries. The user interface includes power button, mode button, volume control, single speaker, headphone jack and LCD display for heart rate, battery and working mode, probe type. SONOLINE A and SONOLINE B includes four interchangeable probes (2MHz normal probe,2MHz water proof probe,3MHz normal probe, 3MHz proof resistance probe), while Baby Sound A and Baby Sound B are integrated with 2MHz probe.
Predicate Device	LifeDop Doppler Ultrasound System **K-number:** K024197 **Product Code:** KNG **Intended Use:** The LifeDop is a hand-held, battery powered audio Doppler device used for detecting fetal heart beats and for blood flow detection in veins and arteries. the product includes four interchangeable probes(OB Late Term, OB Early Term, Vascular pencil probe, Vascular flat face probe) and user replaceable batteries. the user interface includes an on/off button, play/record button, volume control, single 2-1/4" speaker, headphone jack and LCD display for heart rate, battery and waveform information. **Manufactured by:** Summit Doppler Systerms, Inc. Add:5350 Vivian St. Suite A, Arvada, CO 80002-1957 Tel:(303)423-7572 Fax:(303)431-5994
Device Description	Contect Pocket Fetal Doppler includes four models, SONOLINE A, SONOLINE B, Baby Sound A and Baby Sound B. They are handheld, battery powered audio Doppler devices used for detecting fetal heart beats. They are all available for user replaceable batteries. SONOLINE A and SONOLINE B include four interchangeable probes (2MHz normal probe, 2MHz water proof probe, 3MHz normal probe and 3MHz proof resistance probe), while Baby Sound A and Baby Sound B are integrated with 2MHz probe.

Testing	Laboratory testing was conducted to validate and verify that Contec Pocket Fetal Doppler met all design specifications, including electrical safety, EMC, specification. Results of these tests demonstrate compliance to the requirements of all consensus standards
Substantially Equivalent	The proposed device, Contec Pocket Fetal Doppler, is substantially equivalent (SE) to the predicate device LifeDop Doppler Ultrasound System (**K024197**).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Contec Medical Systems Co., Ltd.
% Ms. Diana Hong
General Manager
Shanghai Mid-Link Business Consultant Co., Ltd.
Suite 8D, No. 19, Lane 999, Zhongshan No.2 Road
Shanghai, 200030
CHINA

FEB 2 5 2009

Re: K082480
Trade/Device Name: Contec Pocket Fetal Doppler
Models: Sonoline A/B and Baby Sound A/B
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: KNG
Dated: February 17, 2009
Received: February 17, 2009

Dear Ms. Hong:

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 Contec Pocket Fetal Doppler - Models: Sonoline A/B and Baby Sound A/B, as described in your premarket notification:

Transducer Model Number

2MHz Normal Probe CMS-150-T0
2MHz CW Water Proof CMS-150-T1
3MHz CW Normal Probe CMS-150-T5
3MHz CW Water Proof Probe CMS-150-T2

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 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); 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 contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Exhibit D Indication for Use Form

510(k) Number: K082480
Device Name: Contec Pocket Fetal Doppler

Indications for Use:

Contect Pocket Fetal Doppler (SONOLINE A, SONOLINE B, Baby Sound A and Baby Sound B) are hand-held, battery powered audio Doppler devices used for detecting fetal heart beats. They are all available for user replaceable batteries. The user interface includes power button, mode button, volume control, single speaker, headphone jack and LCD display for heart rate, battery and working mode, probe type.

SONOLINE A and SONOLINE B includes four interchangeable probes (2MHz normal probe,2MHz water proof probe,3MHz normal probe,3MHz water proof probe), while Baby Sound A and Baby Sound B are integrated with 2MHz probe.

Prescription Use __√__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082480

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Device Name: SONOLINE A and SONOLINE B fetal Doppler

Main unit fetal system with either 2MHz CW or 3.0MHz CW

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B/M)	Other (specify)
Ophthalmic										
Fetal					N					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurologica										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletalConventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Comments:

The system consists of main unit with either 2MHz CW or 3.2 MHz CW for fetal applications.
Only one transducer can be used with the main unit at one time

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082480

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Device Name: 2MHz normal probe CMS-150-T0

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B/M)	Other (specify)
Ophthalmic										
Fetal					N					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurologica										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletalConventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Comments:

The above is a 2.0MHz CW transducer for fetal heart detection

(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)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082480

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Device Name: 2MHz CW water proof probe CMS-150-T1

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B/M)	Other (specify)
Ophthalmic										
Fetal					N					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurologica										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletalConventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Comments:

The above is a 2.0MHz CW transducer for fetal heart detection.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082480

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Device Name: 3MHz CW normal probe CMS-150-T5

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B/M)	Other (specify)
Ophthalmic										
Fetal					N					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurologica										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletalConventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Comments:

The above is a 3.0MHz CW transducer for fetal heart detection.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082480

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Device Name: 3MHz CW water proof probe CMS-150-T2

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B/M)	Other (specify)
Ophthalmic										
Fetal					N					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurologica										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletalConventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Comments:

The above is a 3.0MHz CW transducer for fetal heart detection.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082480

Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Device Name: Baby Sound A and Baby Sound B

Main unit fetal system ingreted with 2MHz CW transducer

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

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (B/M)	Other (specify)
Ophthalmic										
Fetal					N					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurologica										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletalConventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Comments:

The system consists of main unit is integrated with 2MHz CW transducer for fetal applications.

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