K024197

JAN 0 3 2003

SAFETY AND EFFECTIVENESS SUMMARY
Summit Doppler Systems, Inc.
LifeDop Doppler Ultrasound System

Name and Address:

Summit Doppler Systems, Inc.
5350 Vivian St. Suite A
Arvada, CO 80002-1957

Phone: (303) 423-7572
Fax: (303) 431-5994

Contact: Ken Jarrell – President

Preparation Date: November 4, 2002

Device Name: LifeDop Doppler Ultrasound System

Common Name: Handheld Fetal and Peripheral Vascular Doppler

Classification:

Class II per:	FR Number	Product Code
Monitor, Ultrasonic, Fetal	884.2660	KNG
Monitor, Bloodflow, Ultrasonic	884.2660	HEP

Indications for Use:

Obstetric (2.1 and 3.2 MHz Probes)
This product will be used to detect fetal heart beats as an aid for determining fetal viability.

Vascular (4.0 and 8.0 MHz Probes)
This product will be used to detect blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

Description: 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.

Substantial Equivalence:

Huntleigh Technologies	Medasonics Incorporated
Manalapan, New Jersey	Newark, California
Dopplex II Pocket Doppler	Cadance Doppler Ultrasound System
K930200, Cleared 6/24/94	K991441 cleared 12/28/99

Technologies Summary: Doppler ultrasound technology is the same as substantially equivalent device shown above. New technology included in the LifeDop is an optional built-in audio recorder.

Clinical Testing: None provided

Conclusion: Based on comparisons of device features, materials, intended use and performance, the LifeDop Doppler is shown to be substantially equivalent to the commercially available and legally marketed device indicated above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Summit Doppler Systems, Inc.
% Mr. Mark Job
510(k) Program Manager
TÜV Product Service
1775 Old Highway 8 NW
Suite 104
NEW BRIGHTON MN 55112-1891

JAN 0 3 2003

Re: K024197
Trade Name: LifeDop Doppler Ultrasound System
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: 85 KNG and HEP
Dated: December 19, 2002
Received: December 20, 2002

Dear Mr. Job:

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 LifeDop Doppler Ultrasound System, as described in your premarket notification:

Transducer Model Number

2.1 MHz CW Fetal Probe
3.2 MHz CW Fetal Probe
4.0 MHz CW Peripheral Vascular Probe
8.0 MHz CW Peripheral Vascular Probe

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 determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

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 (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Attachment C – Indication for Use

Diagnostic Ultrasound Indications for Use Form

LifeDop Doppler Ultrasound System
Main unit fetal system with either 2.1 MHz CW or 3.2 MHz CW
Main unit peripheral vascular system with either 4.0 MHz CW or 8.0 MHz 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 (specify)	Other (specify)
Ophthalmic										
Fetal					N					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethal										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: The system consists of main unit plus either a 2.1 MHz CW or a 3.2 MHz CW transducer for fetal applications, and either a 4.0 MHz CW or a 8.0 MHz CW transducer for peripheral vascular applications. Only one transducer can be used with the main unit at a time.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legan

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K024197

Prescription Use (Per 21 CRF 801.109)

Diagnostic Ultrasound Indications for Use Form

2.1 MHz CW Fetal Probe

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 (specify)	Other (specify)
Ophthalmic										
Fetal					N					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethal										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: The above is for a 2.1 MHz 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 CRF 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K024197

C-2

Diagnostic Ultrasound Indications for Use Form

3.2 MHz CW Fetal Probe

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 (specify)	Other (specify)
Ophthalmic										
Fetal					**N**					
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethal										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: The above is for a 3.2 MHz CW transducer for fetal heart detection

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Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use (Per 21 CRF 801.109)

David K. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K024197

Diagnostic Ultrasound Indications for Use Form

4.0 MHz CW Peripheral Vascular Probe
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 (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethal										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: The above is for a 4.0 MHz CW transducer for peripheral vascular

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Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use (Per 21 CRF 801.109)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K024197

Diagnostic Ultrasound Indications for Use Form

8.0 MHz CW Peripheral Vascular Probe

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 (specify)	Other (specify)
Ophthalmic										
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethal										
Intravascular										
Peripheral Vascular					N					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: The above is for a 8.0 MHz CW transducer for peripheral vascular

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Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use (Per 21 CRF 801.109)

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