K090499

MAR 3 1 2009

SAFETY AND EFFECTIVENESS SUMMARY
Summit Doppler Systems, Inc.
LifeDop 350 Doppler

Name and Address:	Summit Doppler Systems, Inc. 4680 Table Mountain Dr. #150 Golden, CO 80403 Phone: (303) 423-7572 Fax: (303) 431-5994
Contact:	Ken Jarrell – President
Preparation Date:	January 16, 2009
Device Name:	LifeDop 350 Doppler
Common Name:	Portable Doppler, Fetal and Vascular

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 350 Doppler is a portable, battery-powered ultrasound device used for detecting fetal heart beats and also for blood flow detection in veins and arteries. Primarily intended to be table-top, stand or wall mounted.

Substantial Equivalence:

Summit Doppler Systems
Golden, CO
LifeDop Doppler Ultrasound System
K024197, Cleared 1/3/03

Technologies Summary:

Doppler ultrasound technology is the same as substantially equivalent device shown above.

Clinical Testing:

None provided

Conclusion:

Based on comparisons of device features, materials, intended use and performance, the LifeDop 350 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.
% Ms. Dawn Tibodeau
Program Manager, Responsible Third Party Official
TÜV SÜD America, Inc.
1775 Old Hwy 8 NW, Ste 104
NEW BRIGHTON MN 55112-1891

MAR 31 2009

Re: K090499
Trade/Device Name: LifeDop 350 Doppler
Regulation Number: 21 CFR 884.2660
Regulation Name: Fetal ultrasonic monitor and accessories
Regulatory Class: II
Product Code: MAA
Dated: March 16, 2009
Received: March 18, 2009

Dear Ms. Tibodeau:

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 350 Doppler, as described in your premarket notification:

Transducer Model Number

SD2 – 2.1 MHz CW Fetal Probe
SD3 – 3.2 MHz CW Fetal Probe
SD4 – 4.0 MHz CW Peripheral Vascular Probe
SD8 – 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.

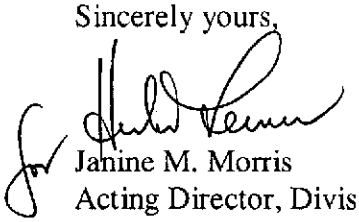
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 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 Paul Hardy at (240) 276-3666.

Sincerely yours,



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

Enclosure(s)

Indications for Use

510(k) Number: K090499

Device Name: LifeDop 350 Doppler

Indications for Use:

Obstetrical:
This product will be used to detect fetal heart beats as an aid for determining fetal viability.

Vascular:
This product will also be used to detect blood flow in veins and arteries for assisting in the detection of peripheral vascular disease.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use ____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090499

Attachment C – Indication for Use

Diagnostic Ultrasound Indications for Use Form

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

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

Additional Comments: 2.1 MHz CW Fetal Probe – Previously cleared K024197

3.2 MHz CW Fetal Probe – Previously cleared K024197

4.0 MHz CW PV Probe – Previously cleared K024197

8.0 MHz CW PV Probe – Previously cleared K024197

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090499

Prescription Use (Per 21 CRF 801.109)

Diagnostic Ultrasound Indications for Use Form

SD2 – 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					P					
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: Previously cleared on K024197, cleared 1/3/03

(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) Diagnostic Ultrasound Indications for Use Form

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K030499

Diagnostic Ultrasound Indications for Use Form

SD3 – 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					P					
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: Previously cleared on K024197, cleared 1/3/03

(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) Diagnostic Ultrasound Indications for Use Form

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K090499

Diagnostic Ultrasound Indications for Use Form

SD4 – 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					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: Previously cleared on K024197, cleared 1/3/03

(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) Diagnostic Ultrasound Indications for Use Form

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090499

Diagnostic Ultrasound Indications for Use Form

SD8 – 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					P					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Additional Comments: Previously cleared on K024197, cleared 1/3/03

(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) Diagnostic Ultrasound Indications for Use Form

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K090499