K063600

SAFETY AND EFFECTIVENESS SUMMARY
Summit Doppler Systems, Inc.
Vista AVS

Name and Address:	Summit Doppler Systems, Inc. 4620 Technology Dr. #100 Golden, CO 80403
	Phone: (303) 423-7572 Fax: (303) 431-5994
	DEC 19 2006
Contact:	Ken Jarrell – President
Preparation Date:	November 3, 2006
Device Name:	Vista AVS
Common Name:	Vascular Ultrasound Monitor

Classification:		FR Number	Product Code
	Class II per: Non-fetal, UltraSound Monitor	892.1540	JAF

Indications for Use:

This device is intended for detection of blood flow in veins and arteries and as an aid for the diagnosis of peripheral vascular disease.

Description:

The Vista AVS™ is a diagnostic ultrasound device used to aid the clinician in obtaining systolic pressure values at the arms, legs and feet. The device will provide a bi-directional Doppler for detecting presence or absence of blood flow, and will control the inflation and deflation of a pressure cuff under direction of the user. Two additional modalities, Pulse Cuff Recording (PCR) and Photoplethysmography (PPG), will provide additional information for the clinician. PCR will be used as a plethysmograph to obtain alternative blood flow waveforms, and the PPG will be used primarily to obtain toe pressures. The unit will calculate Ankle Brachial Index (ABI), Toe Brachial Index (TBI) or segmental values once the clinician has accepted or entered the appropriate pressure values. Waveforms, pressure values, and index results can be printed directly from the device or uploaded using AVS Report™ report generating software and an external user supplied PC via a USB port. The unit can run from an internal power source or from an external power supply, and mounts to a rolling stand.

Substantial Equivalence:

The Vista AVS is substantially equivalent to the cleared device shown below.

IMEXLAB 9100 Diagnostic Ultrasound Device
K973562, Cleared 4/15/98

Technologies Summary:

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

Conclusion:

Based on comparisons of device features, materials, intended use and performance, and user instructions, the Vista AVS is shown to be substantially equivalent to the commercially available and legally marketed device indicated above.

Attachment C – Indication for Use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Summit Doppler Systems, Inc.
c/o Ms. Laura Danielson
Program Manager
TÜV America, Inc.
1775 Old Highway 8
NEW BRIGHTON MN 55112

DEC 19 2006

Re: K063600
Trade Name: Vista AVS
Regulation Number: 21 CFR §892.1540
Regulation Name: Nonfetal ultrasonic monitor
Regulatory Class: Class II
Product Code: JAF
Dated: November 22, 2006
Received: December 4, 2006

Dear Ms. Danielson:

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 Vista AVS, as described in your premarket notification:

Transducer Model Number

5.0BD and 8.0BD MHz CW Peripheral Vascular Probes

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 Ewa Czerska, M.D., at (240) 276-3666.

Sincerely yours,

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

Enclosures

Diagnostic Ultrasound Indications for Use Form

Vista AVS with 5.0BD and 8.0BD Ultrasound Probes
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					E					
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

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

Previously cleared indication is K024197, issued 1/3/03

Additional Comments: The system consists of main unit plus an 5.0BD or 8.0BD probe
Only one transducer can be used with the main unit at a time.

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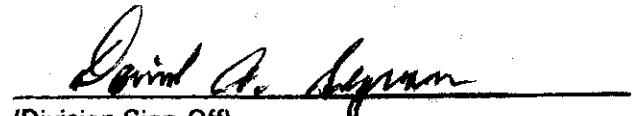
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CRF 801.109)



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063600

Diagnostic Ultrasound Indications for Use Form

5.0BD 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					E					
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 5.0 MHz Bi-Directional Peripheral Vascular Probe

Previously submitted appendix E on K060410 cleared 4/7/06

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063600

Prescription Use (Per 21 CRF 801.109)

Diagnostic Ultrasound Indications for Use Form

8.0BD 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					E					
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 8.0 MHz Bi-Directional Peripheral Vascular Probe

Previously submitted appendix E on K060410 cleared 4/7/06

(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. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K063600

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