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SAFETY AND EFFECTIVENESS SUMMARY
Summit Doppler Systems, Inc.
Vantage ABI

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:	November 30, 2011
Device Name:	Vantage ABI
Common Name:	Plethysmograph

Classification:	Class II:	FR Number	Product Code
	Cardio Vascular Monitoring Device	820.2780	JOM

Indications for Use:	The Vantage ABI is a non-invasive device used to gauge the lower extremity arterial system using pneumatic volume plethysmography recording (PVR) and oscillometric systolic blood pressure to assist in the diagnosis of vascular disease.
Description:	The Vantage ABI performs the ankle-brachial index examination to assist in the diagnosis of peripheral arterial disease. The system will be used to assess peripheral arterial disease using pneumatic volume plethysmography recording (PVR), estimate the systolic blood pressure for each limb and calculate the Ankle Brachial Index. The unit will record a PVR waveform at each ankle and measure pressures in each limb. Four cuffs will be connected. This unit can be powered from its internal battery or from an external line-powered supply.
Substantial Equivalence:	The Vantage ABI is substantially equivalent to the cleared devices shown below. BioMedix, PADnet K042616, Cleared 10/12/2004 Summit Doppler Systems, Vista AVS K063600, Cleared 12/22/2006
Technologies Summary:	This device uses pneumatic volume plethysmography recording (PVR) and Ankle Brachial Index (ABI) to assist in the diagnosis of vascular disease in the same manner as the predicate devices.
Conclusion:	Based on comparisons of device features, materials, intended use and performance, and user instructions, the Vantage ABI 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
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Summit Doppler Systems, Inc.
c/o Ms. Dawn Tibodeau
Responsible Third Party Official
TUV SUD America, Inc.
1775 Old Highway 8 NW
New Brighton, MN 55112-1891

FEB 15 2011

Re: K103693
Trade Name: Vantage ABI
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Code: DXN
Dated: January 28, 2011
Received: January 31, 2011

Dear Ms. Tibodeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

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.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

For W. M.

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K103693

Device Name: Vantage ABI

The Vantage ABI is a non-invasive device used to gauge the lower extremity arterial system using pneumatic volume plethysmography recording (PVR) and oscillometric systolic blood pressure to assist in the diagnosis of vascular disease.

Prescription Use X AND/OR Over-The-Counter-Use _____
(Part 21 CFR 801 Subpart D) (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 Cardiovascular Devices

510(k) Number K103693