Huntleigh Healthcare Limited
Diagnostic Products Division **HUNTLEIGH**

K121108

510(k) Summary
Dopplex Ability

JAN 0 3 2013

Name & Address:	Huntleigh Healthcare Limited - Diagnostic Products Division Unit 35, Portmanmoor Road Cardiff CF24 5HN United Kingdom
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Prepared:	8 December 2012
Contact:	David Moynham – Regulatory Affairs Engineer
Device Name:	Dopplex Ability
Common Name	Hydraulic, pneumatic, or photoelectric plethysmographs

Classification	Class	Product Code	Classification Regulation
	II	JOM	870.2780

Classification Name:	Hydraulic, pneumatic, or photoelectric plethysmographs
Predicate Device:	Vascular Assist (K002186) manufactured by Huntleigh Healthcare Limited, 35 Portmanmoor Road, Cardiff, CF24 5HN, UK
Indications for Use:	Dopplex Ability is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD). Dopplex Ability is intended for rapid measurement of ankle-brachial pressure index (ABPI) or ankle-brachial index (ABI) in adults and pulse volume recording (PVR) / volume plethysmography. It is suitable for use in woundcare assessment, for assessing symptomatic PAD, and as a screening device for PAD. It may also be used on patients with venous or arterial ulcers prior to the application of compression therapy. Dopplex Ability can be used on patients with unilateral lower limb amputation.

The Indications for Use of Dopplex Ability are specific to the measurement of ankle-brachial pressure index (ABPI) or ankle-brachial index (ABI) in adults and pulse volume recording (PVR) for those considered at risk of having or developing peripheral arterial disease (PAD). The Predicate device indication for use, is a broader indication "The device is used for the assessment of blood flow in veins and arteries to assist in the identification of vascular disease". Peripheral arterial disease (PAD) is a sub group of the broader indication "vascular disease". The Predicate device includes the capability of measuring ABPI / ABI and PVR. Clinical data submitted demonstrates the submission

device to provide the performance as indicated for use by a direct comparison of measured indices using both devices. This supports the demonstration of its safety and effectiveness.

Description :

Dopplex Ability is intended to measure a patient's Ankle Brachial Index (ABI) and provide PVR. This is done through an automated process.

The operator places the four colour coded cuffs on each of the patient's limbs as described in the instruction for use and connect to the device.

When connected the operator pushes soft touch button to start measurement, the device then will automatically control the inflation / deflation of the cuffs on each limb and monitor minute variations in individual pressures to determine values to be used for the calculation of the ABI values for both the left and right hand of the patient.

Dopplex Ability uses pneumo-plethysmography uses obtain physiological measurements from patient's limbs. Measurements are conducted as a single occurrence on all four limbs, eliminating any requirement to rest the patient between measurements.

The test period takes approximately 3 minutes. The ABI indices are calculated using an in house algorithm.

ABI values are displayed on the LCD and can also be printed. In addition, records are generated of the Pulse Volume Waveforms (PVR), which may also be displayed on the LCD and can be printed.

Models

Model REF	Device	Features
DA100PB	Dopplex Ability	AC powered with integral printer and battery
DA100P	Dopplex Ability	AC powered with integral printer
DA100B	Dopplex Ability	AC powered with battery
DA100	Dopplex Ability	AC powered

Substantial Equivalence:

Dopplex Ability is substantially equivalent to the cleared device:

Vascular Assist (K002186), cleared 05/02/2001

Technologies Summary:

The predicate device utilises Doppler technology to measure physiological parameters used in calculating into ABI indices. Whereas Dopplex Ability uses pneumo-plethysmography to obtain physiological parameters from patient's limbs

The predicate device has been used in comparison bench testing and clinical assessment to evaluate and demonstrate the equal capability of both devices to measure ABI.

Conclusion:

The non clinical and clinical data detailed within submission demonstrates that the device is safe and effective and performs as well as the legally marketed Predicate device, identified in this summary. With respect to Dopplex Ability to function to measure all four limbs as a single occurrence, the submission device provides improved functionality above that of the legally marketed predicate device without addition concerns regarding safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 0 3 2013

Huntleigh Healthcare Limited
c/o Mr. David Moynham
Senior Regulatory Affairs Engineer
35 Portmanmoor Road
Cardiff, CF24 5HN (UK)

Re: K121108
Trade/Device Name: Dopplex ability
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, pneumatic, or photoelectric plethysmographs
Regulatory Class: Class II (two)
Product Code: JOM
Dated: December 10, 2012
Received: December 12, 2012

Dear Mr. David Moynham:

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,

Bram D. Zuckerman

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

Enclosure

K121108

Indications For Use

510(k) Number: _____

Device Name: **Dopplex Ability**

Indications for Use:

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Prescription Use		Over-The-Counter Use
YES	AND/OR	**NO**
(Part 21 CFR 801 Subpart D)		(Part 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 K121108

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