VASCULAR INSTRUMENTS
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Your Vascular Healthcare Partner

JAN 17 2014

510(k) Summary, Section 5

Date of Preparation: April 26, 2013

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with 21 CFR Sec. 807.92. A 510(k) Statement is not provided.

Company making this submission:

Submitter / Owner	
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Device Name:

Trade/Proprietary Name:	**Smartdop XT with Smart-XT-Link**
Common/Usual Name:	**Ultrasonic transducer**
Regulation Number:	**870.2880**
Product Code:	**JOP**

Substantial Equivalency:

The Smartdop XT is substantially equivalent to other devices intended for use in the noninvasive evaluation of peripheral vascular pathology now in market. The predicate device is the Falcon/Pro manufactured by Viasonix Ltd., Rammana, Israel, with S.E number of K111416.

Device description:

The Smartdop XT with Smart-XT-Link is designed to provide both qualitative and quantitative information. The qualitative information mainly includes visual display of waveform's shapes, including qualitative analysis of Pulse Volume Recordings (PVR), Photoplethysmography (PPG) and Doppler waveforms. The quantitative information is focused primarily on aiding the

examiners in obtaining systolic segmental blood pressures, including the ABI (ankle-brachial index) and TBI (toe-brachial index). Additional quantitative measurements relate to the Doppler blood flow velocity waveforms. Foot skin temperature readings are done with optional temperature probe and can be displayed in either Fahrenheit or Celsius. All tests controlled and stored by computer with Smart-XT–Link software for Windows OS with capabilities to print waveform data and export to electronic health record management systems.

Clinical Applications:

The Smartdop XT with Smart-XT-Link clinical applications is:

ABI and TBI studies	Bi-directional Doppler lower extremity studies
Blood pressure segmental studies	PPG toe pressure & venous reflux studies
PVR arterial studies	Foot temperature readings

Principles:

Doppler blood velocity measurement:

While performing Doppler waveform test on Doppler Arterial Testing, blood flow velocity is detected through the ultrasound which is transmitted from probe to patient body and is reflected by the blood (hemolytic, etc.).

The unit amplifies the high frequency oscillation output and then supplies it to the transmitter transducer. It is converted to ultrasound by the transducer and the ultrasound is transmitted to external objects. The ultrasound moves straight through biophysical object, and is reflected by the moving object (blood flow, fetal heartbeat etc.).

The reflected ultrasound is received by the receiving transducer and is converted into electric signals again.

The converted signals are amplified and then detected. After removing unnecessary noise from the signals and improving S/N ratio at the filter circuit, the Doppler shift signals are amplified and are converted to audible sounds through a speaker. Simultaneously, the Doppler shift signals are applied to the CPU and converted to blood flow velocity waveform signals which can be displayed.

Doppler blood pressure measurement:

The cuff pressure at the first signal is the systolic pressure. After confirming a return of the rhythmical blood flow signals, the CPU opens the air valve to dump the cuff pressure and converted to systolic pressure waveform signals which can be displayed.

Oscillometry:

While taking blood pressure on Automatic Arterial Testing screen and deflating cuff for arm or leg after the inflation, the unit detects oscillations of the blood vessel synchronizing with each heart beat and determines the systolic pressure based on oscillometry algorithm.

Photoplethysmography:

While taking toe pressure with PPG probe as well as performing PPG venous reflux study, the unit senses the reflection of light from the hemoglobin of the red blood cells in surface vessels by utilizing infrared light with the probe.

Pneumoplethysmography (PVR):

While performing PVR waveform test for toes and legs on either Automatic or Doppler Arterial Testing, the unit assesses changes in blood volume in the tissues beneath an inflated cuff. Alterations in pressure are transmitted to a pressure transducer that records the volume changes through the cardiac cycle to produce a waveform.

Probes and Cuffs:

- Cuffs: Up to 14: Refer the following cuff size as example:

VC-10: 8 pcs. VC-12: 2 pcs.	For brachial, above knees, below knees ankles and high thighs
DVC-1.9: 2 pcs.	For great toes
VC-7.5: 2 pcs.	For transmetatarsal

- Probes:

	Model name	Freq.	Probe power (In situ)
Doppler probe (8MHz):	BT8M05S8C (A)	8MHz	390 mW/cm^2 or less
Temperature probe:	TP-01		

Indication for Use Statement:

The Smartdop XT is intended for use in the non-invasive evaluation of peripheral vascular pathology in patients. It detects systolic pressures for ankle-brachial index (ABI), toe- brachial index (TBI), and arterial and venous blood flow in extremities. Measurements are provided utilizing cuffs and/or Doppler probe. The optional foot temperature probe provides skin temperature readings on the foot. Collected data is captured and stored with Smart-XT-Link software that includes capabilities to print waveforms and export to into the facility's electronic health records.

It is not intended to be used in fetal applications or used inside the sterile field.

Testing:

The Smartdop XT was designed to meet the following Standards and Guidance:

- IEC 60601-1 Medical electrical equipment 2007
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: Collateral Standard Electromagnetic compatibility (2007).
- IEC 60601-2-37 Medical electronic equipment – Part 2-37: Particular requirement for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (2007-08).
- IEC 62304 Medical device software – Software life cycle processes (2006-05).
- ISO 14971, Medical devices – Application of risk management to medical devices (2007-10-01).
- ANSI/AAMI/IEC 80601-2-30:2009 Medical electrical equipment Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
- ANSI/AAMI/ISO 81060-1:2007 Non-invasive sphygmomanometers Part 1: Requirements and test methods for non-automated measurement type.

The Smartdop XT testing was completed with acceptance to the above Standards. The Smartdop XT device probes and cuff are previous FDA released devices, with complete and accepted testing and validation.

The Smartdop XT system have been subjected to Bio-Compatibility, Electrical Safety, Mechanical Safety, Acoustic Output, EMC emissions and immunity, and performance testing by certified laboratories. Internally the Smartdop XT is subjected to unit testing, verification, performance testing, and validation to ensure that the device(s) meet all of their functional specifications listed in the Device Master Record.

The Smartdop XT labeling includes instructions for safe and effective use, warning, cautions and guidance for use.

Literature Review:

A review of the literature pertaining to the safety of the Smartdop XT non-invasive peripheral vascular diagnostic systems has been conducted and appropriate safeguards have been incorporated in the design of the Smartdop XT non-invasive peripheral vascular diagnostic systems.

Differences between Smartdop XT and Predicate:

The general method of device construction and technology are the same. The Falcon/Pro computer screen has "touch screen" capabilities, the Smartdop XT does not. The Smartdop XT has four more pressure ports that the Falcon/Pro. The Smartdop XT does not have frequency analysis waveform display, only bidirectional Doppler display.

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Conclusions:

The conclusion drawn from these tests is that the Smartdop XT non-invasive peripheral vascular diagnostic system is equivalent in safety and efficacy to the predicate device.

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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

January 17, 2014

Koven Technology, Inc.
c/o Harvey Knauss
Delphi Consulting Group
11874 South Evelyn Circle
Houston, TX 77071-3404 US

Re: K131623
Trade/Device Name: Smartdop xt
Regulation Number: 21 CFR 870.2880
Regulation Name: Flow Meter, Blood, Cardiovascular
Regulatory Class: Class II
Product Code: JOP
Dated: December 17, 2013
Received: December 19, 2013

Dear Harvey Knauss:

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 contact 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Owen P. Faris -S

for

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

Enclosure

Indications for Use Statement

510(k) Number: K131623

Device Name: **Smartdop XT**

The Smartdop XT is intended for use in the non-invasive evaluation of peripheral vascular pathology in patients. It detects systolic pressures for ankle-brachial index (ABI), toe- brachial index (TBI), and arterial and venous blood flow in extremities. Measurements are provided utilizing cuffs and/or Doppler probe. The optional foot temperature probe provides skin temperature readings on the foot. Collected data is captured and stored with Smart-XT-Link software that includes capabilities to print waveforms and export to into the facility's electronic health records.

It is not intended to be used in fetal applications or used inside the sterile field.

Prescription Use **YES** AND/OR Over-The Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2014.01.17 15:46:50 -05'00'