January 15, 2020

Medeia, Inc.
% Daniel Lehtonen
Regulatory Consultant
Compliance and Regulatory Services LLC
3771 Southbrook Dr
Dayton, Ohio 45430

Re: K191266
Trade/Device Name: VitalScan ANS
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, Pneumatic, or Photoelectric Plethysmographs
Regulatory Class: Class II
Product Code: JOM, DPS, DXN
Dated: December 11, 2019
Received: December 16, 2019

Dear Daniel Lehtonen:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer Shih
Assistant Director (Acting)
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191266

Device Name

VitalScan ANS

Indications for Use *(Describe)*

VitalScan ANS is intended for non-invasive measurements of pulse waveforms by photoelectric plethysmography (PPG), heart rate electrocardiograph (ECG), Heart Variability measurements (HRV) and blood pressure (NIBP) in response to paced respiration and controlled testing procedures for physician assessment of the Cardiovascular Systems.

VitalScan ANS also measures/calculates a patient's Brachial and Ankle Blood Pressure, Ankle Brachial Pressure Index (ABPI) and Ankle Brachial Index (ABI) and provides Pulse Volume Recording (PVR) / volume plethysmography for assessing development of peripheral arterial disease (PAD).

The device is intended for use on transitional adolescents and adults, including those with unilateral lower limb amputation, in medical clinics, healthcare practices and out-patient departments of hospitals.

The physician has the responsibility of interpreting the significance of the resulting data.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

This summary of 510(k) information is submitted in accordance with the Requirements of Safe Medical Device systems Act 1990 and 21 CFR Sec. 807.92

510(k) Number: **K191266**

a1 APPLICANT INFORMATION:

Date Prepared: 03 May 2019

Name: Medeia, Inc.

Address: 7 W. Figueroa Street
Suite 300
Santa Barbara, CA, 93101

Contact Person: Slav Danev

Phone Number: +1 800 433 4609

Fax Number: +1 800 433 4609

Email: danev@medeia.com

a2 NAME OF DEVICE:

Trade Name: VitalScan ANS

Common Name: Plethysmograph, photoelectric, pneumatic or hydraulic

Classification Name: Plethysmograph, photoelectric, pneumatic or hydraulic
21 CFR 870.2780 (JOM)
Electrocardiograph
21 CFR 870.2340 (DPS)
Noninvasive blood pressure measurement system
21 CFR 870.1130 (DXN)

a3 PREDICATE DEVICES:

Primary Predicate Device: K083735; ANSHA-QHRV1

Secondary Predicate Device: K101983; Critical Care Assessment

Secondary Predicate Device: K172655; ABPI MD

Reference Device: K012647; Tonoport V

The FDA database for recalls was searched on 20 March 2019 during the preparation of the 510(k) submission and no recalls for the devices noted above were found.

a4 INDICATIONS FOR USE:

VitalScan ANS is intended for non-invasive measurements of pulse waveforms by photoelectric plethysmography (PPG), heart rate electrocardiograph (ECG), Heart Variability measurements (HRV) and blood pressure (NIBP) in response to paced respiration and controlled testing procedures for physician assessment of the Cardiovascular Systems.

VitalScan ANS also measures/calculates a patient's Brachial and Ankle Blood Pressure, Ankle Brachial Pressure Index (ABPI) and Ankle Brachial Index (ABI) and provides Pulse Volume Recording (PVR) / volume plethysmography for assessing development of peripheral arterial disease (PAD).

The device is intended for use on transitional adolescents and adults, including those with unilateral lower limb amputation, in medical clinics, healthcare practices and out-patient departments of hospitals.

The physician has the responsibility of interpreting the significance of the resulting data.

a5 DESCRIPTION OF THE DEVICE:

VitalScan ANS system collects multi-parameter patient data including: Electrocardiography (ECG), Plethysmogram (PPG), Pulse Volume Recording (PVR), Blood Pressure, Heart Rate, and Peripheral capillary Oxygen saturation (SpO_2).

The system comprises: USB plug and play device hardware and Software installed on a computer.

VitalScan ANS is intended to measure a patient's variations in the heart rate (R-R beat-to-beat intervals from ECG) and perform Heart Rate Variability (HRV) analysis to assess Autonomic Nervous System (ANS) Function;

VitalScan ANS also measure a patient's Brachial and Ankle Blood Pressure, Ankle Brachial Pressure Index (ABPI) and Ankle Brachial Index (ABI) and provides Pulse Volume Recording (PVR) / volume plethysmography for assess the risk of developing peripheral arterial disease (PAD).

The results are saved in a backup and can also be printed.

The device does not provide any direct diagnosis rather the device provides information to the physician for inclusion in their decision making process.

a6 TECHNOLOGICAL CHARACTERISTIC COMPARISON:

VitalScan ANS product share similar device characteristics, intended use, performance, specifications, sensors and is the same in design, function, and application to the predicate devices.

The comparison table, beginning on page 5, demonstrates that the VitalScan ANS device is substantially equivalent to the predicate devices. The nonclinical data support the safety of the device and the hardware and software verification and validation demonstrate that the VitalScan ANS device should perform as intended in the specified use conditions.

Based on comparisons of device technological characteristics, features, materials, intended use and performance the VitalScan ANS has been shown to be substantially equivalent to the commercially available predicate devices.

b1 NON-CLINICAL TESTING:

The VitalScan ANS device was subjected to the following non-clinical performance testing:

Bench testing was carried out on the following characteristics:

- Electrocardiograph (ECG)
- Heart rate variability (R-R interval)
- Heart rate
- SpO_2 and Plethysmogram
- Blood-Pressure Measurement accuracy
- Communication, data transmission and storage integrity
- Electromagnetic compatibility (EMC)
- Electrical safety testing
- Software verification and validation testing
- Biocompatibility verification

In addition to the above, usability testing was also conducted.

Referenced Standards and Performance Testing:
The VitalScan ANS device was tested and meets the applicable requirements of following performance Standards and is in accordance with FDA Class II Special Controls Guidance Document:

- IEC 60601-1 Medical Electrical Equipment - Part 1: Basic safety and essential performance Ed 3.1 2005+A1:2012
- IEC 60601-1-2 Medical Electrical Equipment - Basic safety and essential performance-EMC-Edition 3: 2007-03
- IEC 60601-1-6 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability; Edition 3.1 2013-10
- AAMI / ANSI 60601-2-27 Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment 2011
- ISO 80601-2-61 Particular requirements for basic safety and essential performance of pulse oximeter equipment 2011

- AAMI / ANSI / IEC 80601-2-30 Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers 2009 + A1:2013
- AAMI / ANSI EC57 - Testing and reporting performance results of cardiac rhythm and st-segment measurement algorithms 2012 [Select clauses to support device performance]

Software Verification and Validation Testing

Software verification and validation testing were conducted following the FDA guidance document for software contained in medical devices. The software was considered to be a "moderate" level of concern since a failure or latent flaw could indirectly result in a minor injury to the patient through incorrect or delayed information or through action of the operator.

b2 CLINICAL TESTING:

No Clinical testing was necessary to determine substantial equivalence.

b3 CONCLUSIONS DRAWN FROM TESTING:

Based on information obtained on the predicate device with reference to the design specification, electrical safety / EMC testing and intended use, the VitalScan ANS device was subjected to the same type of testing. The results support the conclusion that the VitalScan ANS device is substantially equivalent to the Predicate devices.

Comparison Table

In section a3 Predicate Devices section of this Summary document, The Critical Care Assessment (CCA) device (K101983) is included as a predicate. The Critical Care Assessment device is a re-labeled ANSHA-QHRV1 device with the only difference being the name of the device. The following comparison table includes only the ANSHA-QHRV1 device for direct comparison as all rows for the CCA device would be identical.

Feature	VitalScan ANS	Primary Predicate	Secondary Predicate	Reference Device	Substantial Equivalence Comments
		ANSHA-QHRV1	ABPI MD	Tonoport V	
510(k) Number	**Subject Device**	**K083735**	**K172655**	**K012647**	--
Device name	VitalScan ANS	ANSHA-QHRV1	ABPI MD	Tonoport V	--
Manufacturer	Medeia Ltd.	Medeia Ltd.	MESI	PAR Medizintechnik GmbH	--
Regulation Numbers	21 CFR 870.2780 21 CFR 870.2340 21 CFR 870.1130	21 CFR 870.2780 21 CFR 870.2340	21 CFR 870.2780	21 CFR 870.1130	CFR numbers of the subject device include those of the predicate and reference devices
Product Codes	JOM, DPS, DXN	JOM, DPS	JOM	DXN	Product Codes of the subject device include those of the predicate and reference devices

Feature	VitalScan ANS	Primary Predicate	Secondary Predicate	Reference Device	Substantial Equivalence Comments
		ANSHA-QHRV1	ABPI MD	Tonoport V	
Indications for Use	VitalScan ANS is intended for non-invasive measurements of pulse waveforms by photoelectric plethysmography (PPG), heart rate electrocardiograph (ECG), Heart Variability measurements (HRV) and blood pressure (NIBP) in response to paced respiration and controlled testing procedures for physician assessment of the Cardiovascular Systems. VitalScan ANS also measures/calculates a patient's Brachial and Ankle Blood Pressure, Ankle Brachial Pressure Index (ABPI) and Ankle Brachial Index (ABI) and provides Pulse Volume Recording (PVR) / volume plethysmography for assessing development of peripheral arterial disease (PAD). The device is intended for use on transitional adolescents and adults, including those with unilateral lower limb amputation, in medical clinics, healthcare practices and out-patient departments of hospitals. The physician has the responsibility of interpreting the significance of the resulting data.	ANSHA-QHRV1 is intended for non-invasive measurements of pulse waveforms by photoelectric plethysmography and heart rate electrocardiograph. The system is intended for use of patients in medical clinics, healthcare practices and in out-patient department of hospitals.	The ABPI MD system is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD). The ABPI MD system is intended for the rapid measurement of ankle-brachial pressure index (ABPI), or ankle-brachial index (ABI) and pulse volume recording (PVR) / volume plethysmography in adults. It is suitable for wound care 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 application of compression therapy. The ABPI MD system can be used on patients with unilateral lower limb amputation. The ABPI MD system is intended to be used to spot-check patients. The ABPI MD system provided information regarding patient risk. The physician has the responsibility of making proper judgements based on this information.	**[Excerpt of IFU]** The Tonoport V is a compact, lightweight, patient-borne, non-invasive blood pressure (NIBP) bolter using the oscillometric method. The cuff is borne on the upper arm and an electrical pump inside the device generates the pressure in the cuff….Tonoport V is intended to be used for measuring the systolic, diastolic, mean blood pressure and the heart rate of human beings for periods up to 30 hours. The intended patient populations are adults and children (but not neonates) with a circumference of the upper arm in the range of 17 cm to 42 cm….A measurement with Tonoport V is combined with other measurements and medical examinations at the patient, so that a diagnosis about the patient's health condition depends not alone from the measurement of the Tonoport V.	There are no differences in the intended use of the devices. The indications for use are clarified, but not changed. The measurements made by the ANSHA-QHRV1 are used for the same purposes as the VitalScan ANS device – analysis of HRV, PWV, and PVR. The VitalScan ANS uses the same algorithms as the ANSHA-QHRV1 for PPG and ECG acquisition and analysis. The measurements made by the ABPI-MD device are used for assessing symptomatic PAD or for screening for PAD. The VitalScan ANS makes measurements for the same purposes. The VitalScan ANS uses the same algorithm as the Tonoport V for NIBP measurements. The VitalScan ANS and predicate/reference devices are used for the adult population in professional settings and a medical professional is responsible for interpreting the data / determining its significance related to the patient's health.

Feature	VitalScan ANS	Primary Predicate	Secondary Predicate	Reference Device	Substantial Equivalence Comments
		ANSHA-QHRV1	ABPI MD	Tonoport V	
Measurements	HRV – by ECG using electrodes placed on the chest or on hands. The monitoring program has been developed according to the standards and mathematical procedures for short-term HRV Autonomic nervous system analysis as well as for performing and evaluating blood pressure, blood flow and autonomic challenge tests. Test Administration: Cardio respiratory Coupling and Autonomic Balance (Sympathetic and Parasympathetic Tone), Autonomic dysregulation Stress Analysis. Time: 4.30 minutes Parasympathetic Breathing Reflex. Time: 1 minute Sympathetic Vasoconstriction Reflex; Time: 1.30 minutes Orthostatic Test, Cardiovascular Reflex, Cardiovascular Fitness Analysis Time: 5.00 minutes Systolic, Diastolic and Ankle Brachial pressures using the oscillometric method	HRV – by ECG using electrodes placed on the chest or on hands. The monitoring program has been developed according to the standards and mathematical procedures for short-term HRV Autonomic nervous system analysis as well as for performing and evaluating blood flow and autonomic challenge tests. Test Administration: Cardio respiratory Coupling and Autonomic Balance (Sympathetic and Parasympathetic Tone), Stress Analysis. Time: 4.30 minutes Parasympathetic Breathing Reflex. Time: 1 minute Sympathetic Vasoconstriction Reflex Time: 1.30 minutes Orthostatic Test, Cardiovascular Reflex, Fitness Analysis Time: 5.00 minutes	Ankle brachial pressure index using the oscillometric method Systolic blood pressure using the oscillometric method Diastolic blood pressure using the oscillometric method Heart rate using the oscillometric method	Measuring the systolic, diastolic and mean blood pressure and the heart rate using the oscillometric method	For HRV / PWV / PVR the VitalScan ANS device is identical to the ANSHA-QHRV1. The measurements and test protocol are the same between the two devices. For ABPI / ABI / PAD assessment the VitalScan ANS is the same are the ABPI-MD device. Both devices use the oscillometric method to make determinations.

Feature	VitalScan ANS	Primary Predicate	Secondary Predicate	Reference Device	Substantial Equivalence Comments
		ANSHA-QHRV1	ABPI MD	Tonoport V	
Alarms	No alarms as part of the device	No alarms as part of the device	No alarms are part of the device	Unknown	Same – no alarms are provided for the predicate devices.
General Specifications					
Dimensions	24 x 8.4 x 20 cm	110 x 70 x 11 mm	25 x 7.3 x 20 cm	80 x 27 x 100 mm	Similar – dimensions / mass doesn't impact device function or raise different questions of safety or effectiveness.
Weight	1000 grams	100 grams	600 grams	199 grams	
Display	PC	PC	4.3" color LCD screen	30.0 mm x 10.5 mm	Same as ANSHA-QHRV1
Energy source	5VDC/1.6 A + USB from laptop	USB from laptop	Rechargeable lithium polymer battery	Powered by two AA size batteries	VitalScan ANS uses the USB for powering the device and an external power supply for powering the NIBP function
Target population	Adult	Adult	Adult	Adults and children, but not neonates	Same
Where used	Clinical environment	Clinical environment	Clinical environment	In hospital	Same
PC Data transmission	USB	USB	USB	USB or RS-232	Same
Temperature and humidity range	Working environment: 10 to 40°C, 30 to 75% Relative air humidity, IPX1 protection. Transport and storage: -20 to 70°C, up to 90% Relative air humidity.	Working environment: 10 to 40°C, 30 to 75% Relative air humidity, IPX0 protection. Transport and storage: -20 to 70°C, up to 90% Relative air humidity.	Working environment: 10 to 40°C, 30 to 85% Relative air humidity, IPX0 protection. Transport and storage: 0 to 60°C, up to 85% Relative air humidity.	Working environment: 10 to 40°C, 30 to 75% Relative air humidity, IPX0 protection. Transport and storage: -20 to 70°C, up to 90% Relative air humidity.	Similar – Change from IPX0 to IPX1 does not affect measurements. Change was necessitated by testing to the device to ISO 80601-2-61 which mandates IPX1 for devices not used for transport
Standards	60601-1 60601-1-2 60601-1-6 60601-2-27 80601-2-30 80601-2-61	60601-1 60601-2-27 (limited clauses)	60601-1 60601-1-2 60601-1-6 80601-2-30	80601-2-30	Similar – the VitalScan ANS was tested to the full suite of standards based on the functions included. This testing does not raise different questions of safety or effectiveness

Feature	VitalScan ANS	Primary Predicate	Secondary Predicate	Reference Device	Substantial Equivalence Comments
		ANSHA-QHRV1	ABPI MD	Tonoport V	
PHYSIOLOGICAL PARAMETERS					
ECG					
Method	ECG lead wires attached to disposable electrodes to the skin	ECG lead wires attached to disposable electrodes to the skin			Same as ANSHA-QHRV1
Resolution	24 bit	16 bit			Similar. Increased resolution improves noise reduction. There is no impact on device function. No different questions of safety or effectiveness are raised.
Input impedance	> 20 Mohm	> 20 Mohm			Same as ANSHA-QHRV1
Common mode rejection	-80dB - 100dB	-80dB - 100dB			Same as ANSHA-QHRV1
Sampling frequency	1000, 500, 200 Hz	800, 400 and 200 Hz			Similar. For HRV analysis the default sampling frequency is set at 200 Hz via software in both devices. The sampling frequency options do not impact device function. No different questions of safety or effectiveness are raised.
Channels	3 or 12 channels	3 channels			Similar to ANSHA-QHRV1. Added ECG leads does not impact measurement functionality. Both 3 and 12 lead cables were evaluated to 60601-2-27
QRS detection	Yes - 99.8%	Yes - 99.8%			Same as ANSHA-QHRV1
Permanent Display	Not Provided	Not Provided			Same as ANSHA-QHRV1
Applied parts in contact with the patient	ECG Electrodes	ECG Electrodes			Same as ANSHA-QHRV1

Feature	VitalScan ANS	Primary Predicate	Secondary Predicate	Reference Device	Substantial Equivalence Comments
		ANSHA-QHRV1	ABPI MD	Tonoport V	
HEART RATE					
Method	QRS detection	QRS detection	Oscillometric method	Oscillometric method	Same as ANSHA-QHRV1
Range	38 - 250 bpm	40 - 200 bpm	30 - 199 bpm	35 - 240 bpm	Similar – minor change doesn't impact device function or raise different questions of safety or effectiveness
Accuracy	± 2 bpm	± 2 bpm	± 5% of value	Not Specified	Same as ANSHA-QHRV1
BLOOD PRESURE					
Measurement types	Oscillometric measuring method during deflation of the cuff		Oscillometric measuring method during deflation of the cuff	Oscillometric measuring method during deflation of the cuff	Same as ABPI-MD
Measurement ranges	Systolic: 60 to 260 mmHg Diastolic: 40 to 220 mmHg BP Pulse rate (HR): 35 to 240 min-1		39 – 242 mmHg Systolic 40 – 180 mmHg Diastolic 30 to 199 bpm (Pulse)	Systolic: 60 to 260 mmHg Diastolic: 40 to 220 mmHg BP Pulse rate (HR): 35 to 240 min-1	Same as Tonoport V
Limit values of measurement errors	ABPI: ± 0.1 Empirical Standard Deviation Systolic 4.6 mmHg Diastolic 4.4 mmHg		± 0.1 ABPI ± 3 mmHg (BP) ± 5% of value (Pulse)	Empirical Standard Deviation Systolic 4.6 mmHg Diastolic 4.4 mmHg	Same as Tonoport V
Cuffs inflation and deflation	Automatic inflation using an air pump and deflation using an electromagnetic valve. Max 300 mmHg		Automatic inflation using an air pump and deflation using and electromagnetic valve	Automatic inflation using an air pump and deflation using an electromagnetic valve. Max 300 mmHg	Same as Tonoport V
Pulse Volume / Plethysmography	Pneumo-plethysmography method using the cuffs measuring the blood pressure values: Plethysmography displayed at the inflation and deflation pressure		Pneumo-plethysmography method using the cuffs measuring the blood pressure values: Plethysmography displayed at the inflation and deflation pressure	N/A	Same as ABPI-MD

Feature	VitalScan ANS	Primary Predicate	Secondary Predicate	Reference Device	Substantial Equivalence Comments
		ANSHA-QHRV1	ABPI MD	Tonoport V	
Applied parts in contact with the patient	2 or 4 cuffs, tubes and bladders		3 cuffs, tubes and bladders	1 cuff, tube and bladder	Similar – The VitalScan ANS allows the user to place a cuff on each arm and each leg simultaneously rather than having to move a cuff from one limb to another.
OXYGEN SATURATION					
Method	Photo plethysmogram on finger. Infrared: 910 nm @ 1.2 mW maximum average Red: 660 nm @ 0.8 mW maximum average	Photo plethysmogram on finger. Infrared: 910 nm @ 1.2 mW maximum average Red: 660 nm @ 0.8 mW maximum average			Same as ANSHA-QHRV1. Only difference between subject and predicate device is that the VitalScan ANS device was fully tested to 80601-2-61 for safety and performance
Range	70-100%	70-100%			
Accuracy	± 2 digits (from 70-100%)	± 2 digits (from 70-100%)			