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

February 19, 2016

Suntech Medical, Inc.
Charles Setzer
Quality & Regulatory Affairs Manager
507 Airport Blvd, Suite 117
Morrisville, North Carolina 27560

Re: K151520
Trade/Device Name: Oscar 2
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 26, 2016
Received: January 27, 2016

Dear Charles Setzer:

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.

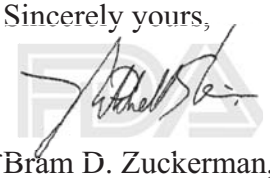
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Industry and Consumer Education 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 Industry and Consumer Education 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 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)* K151520

Page 1 of 1

Device Name
Oscar 2, Model 250

Indications for Use *(Describe)*

The Oscar 2, Model 250 system is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with AccuWin Pro, a PC-based computer program for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult and pediatric (> 3yrs.) patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses.

Optionally, The Model 250 will provide a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively through the use of a brachial cuff.

It is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits (excludes pediatric subjects).

BlueTooth, wireless connectivity will be offered as an option.

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.

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SunTech Medical, Inc.
Abbreviated 510(k) Submission
Oscar 2, Model 250
510(k) Summary

(1) Submitter information

Name:	SunTech Medical, Inc
Address:	507 Airport Boulevard Suite 117 Morrisville, North Carolina 27560-8200
Telephone:	919.654.2334
FAX:	919.654.2301
Contact person:	Charles Setzer (Official Correspondent). SunTech Medical 507 Airport Boulevard Suite 117 Morrisville, North Carolina 27560-8200 Tel: 919-654-2334 Fax: 919-654-2301
Date prepared:	26JAN2016

(2) Name of Device

Trade Name:	Oscar 2, Model 250
Common Name:	NIBP Monitor
Classification name:	Noninvasive Blood Pressure Measurement System, DXN 870.1130

(3) Legally-marketed predicate devices

The Oscar 2, model 250, is a modification of the Oscar 2, model 222, ambulatory blood pressure monitor, K003004

The Oscar2, model 250, uses Atcor Medical's Sphygmocor Xcel, K122129, as a predicate device for the implementation of central BP.

The Oscar2, model 250, uses I.E.M. GmbH's ABPM 7100 PWA, K140928, with Hyperrtension Management Software Client 4.7 as a predicate device for central BP outside the medical clinic and for bluetooth operations.

The Oscar2, model 250, uses Mortara Instruments' Ambulo 2400 Ambulatory Blood Pressure Monitoring System, K133989, as a predicate for use of ABPM in the pediatric population.

The Oscar 2, model 250, is substantially equivilent to these devices.

(4) Description

The Oscar 2 monitor is worn by the patient on a waist belt and is connected to an ABPM blood pressure cuff around the non-dominant upper arm. The cuff is inflated automatically at intervals which can be programmed during setup. Blood pressure is measured by the oscillometric method which senses pressure waves in the artery when occluded by pressure in the cuff. Measurement of the frequency of the pressure waves enables heart rate to also be measured.
The Oscar 2 is a small hand-held or portable device, approximately 120 x 72 x 32 mm in size and weighs approximately 284 g including batteries. For convenience during a 24 hour study, the device can be worn with an optional pouch on a belt shoulder strap. The ABPM cuff is connected to the device, and the control buttons provide stop/start, day/night switch, event marking and dosage response capabilities. The LCD graphic screen allows for function monitoring and appropriate icon display. The device uses a microprocessor with software, which is not accessible to the user. The unit is powered by two (2) "AA" batteries located at the rear of the device. A USB port connection is used to download the patient information into the AccuWin Pro™ v4 software located on a separate PC. The AccuWin components include a flash drive and a USB cable.

(5) Intended Use

The Oscar 2, Model 250 system is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with AccuWin Pro, a PC-based computer program for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult and pediatric (> 3yrs.) patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses.

Optionally, The Model 250 will provide a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively through the use of a brachial cuff.

It is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits (excludes pediatric subjects).

BlueTooth, wireless connectivity will be offered as an option**.**

(6) Comparison to Predicate Devices

The device has the same basic construction as the primary predicate device. Both modified and original devices share the same specifications, measurement ranges, and intended uses. The devices are manufactured from the same types of materials using the same production methods and are intended for the same patient populations.

PREDICATE DEVICE TABLE

ATRIBUTE	NEW DEVICE	PRIMARY PREDICATE	SECONDARY PREDICATE (A)	SECONDARY PREDICATE (B)	SECONDARY PREDICATE (C)	COMPARISON
	SUNTECH MEDICAL INC. OSCAR 2, MODEL 250	SUNTECH MEDICAL INC. OSCAR 2, MODEL 222 (K003004)	ATCOR MEDICAL PTY LTD SPHYGMOCOR XCEL SYSTEM (K122129)	I.E.M GMBH. ABPM 7100 PWA (K140928)	MORTARA INSTRUMENTS AMBULO 2400 (K133989)	
Indications for Use	The Oscar 2, Model 250 system is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with AccuWin Pro, a PC-based computer program for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult and pediatric (> 3yrs.) patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses. Optionally, the Model 250 will provide a derived ascending aortic blood pressure waveform and a range of	The Oscar 2, Model 222 system is a non-invasive oscillometric ambulatory blood pressure monitor that is intended to be used with AccuWin Pro, a PC-based computer program for the recording and displaying of up to 250 measurements of systolic and diastolic blood pressure and heart rate. It is intended for use as an aid or adjunct to diagnosis and treatment when it is necessary to measure an adult patient's systolic and diastolic blood pressures over an extended period of time. The system is only for measurement, recording, and display. It makes no diagnoses.	The SphygmoCor® XCEL provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. These measurements are provided non-invasively through the use of a Brachial cuff. It is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits. Additionally, the SphygmoCor XCEL System automatically measures Systolic blood pressure and Diastolic blood pressure. The SphygmoCor XCEL Pulse Wave Velocity (PWV) option is intended to obtain PWV	The ABPM 7100 is an automated microprocessor controlled ambulatory blood pressure monitor (ABPM) which monitors, accumulates and stores: heart beat (rate), systolic and diastolic data of an individual **adult patient** (in the patient's environment) for a session which may last 24 hours. The ABPM 7100 in combination with Hypertension Management Software Client Server (HMS-CS) provides a derived ascending aortic blood pressure waveform and a range of central arterial indices. Use of the Augmentation Index AIx only is restricted to patients of age 40 and above. It is used with a standard cuff blood pressure	The Ambulo 2400 Ambulatory Blood Pressure Monitor is indicated for use in **adult & pediatric** patient populations; it is not indicated for use with neonates. The Ambulo 2400 Ambulatory Blood Pressure Monitor is designed to measure systolic and diastolic blood pressure and pulse rate of adults and pediatric patients, using the oscillometric method on a cuffed arm.	The Oscar 2, Model 250 is identical to the Primary Predicate and Secondary Predicates B & C (***Table 2***) in the non-invasive BP mode for use as an aid or adjunct for diagnosis and treatment when it is necessary to measure an adult patient's systolic and diastolic blood pressures over an extended period of time (i.e. ABPM) Oscar 2 , Model 250 is identical in its indications for use for adults and pediatrics (>3 yrs) using Predicate C (***Table 2***) The Oscar 2, Model 250 identical to Predicate A and Predicate B (***Table 2***) regarding indications for Central BP subjects Oscar 2, Model 250 excludes Pulse Wave Velocity (PWV).

ATRIBUTE	NEW DEVICE	PRIMARY PREDICATE	SECONDARY PREDICATE (A)	SECONDARY PREDICATE (B)	SECONDARY PREDICATE (C)	COMPARISON
	SUNTECH MEDICAL INC. OSCAR 2, MODEL 250	SUNTECH MEDICAL INC. OSCAR 2, MODEL 222 (K003004)	ATCOR MEDICAL PTY LTD SPHYGMOCOR XCEL SYSTEM (K122129)	I.E.M GMBH. ABPM 7100 PWA (K140928)	MORTARA INSTRUMENTS AMBULO 2400 (K133989)	
	central arterial indices. These measurements are provided non-invasively through the use of a brachial cuff. It is to be used on those patients where information related to ascending aortic blood pressure is desired but the risks of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits. (excludes pediatric subjects) BlueTooth wireless connectivity will be offered as an option		measurements. The PWV option is used on adult patients only.	measurement. It is used in those patients where information related to the ascending aortic blood pressure is desired but in the opinion of the physician, the risk of cardiac catheterization procedure or other invasive monitoring may outweigh the benefits. BlueTooth wireless connectivity is offered as an option		The Oscar 2, Model 250 is substantially equivalent to Secondary Predicates (B)
SYSTEM PHOTO						The Oscar 2, Model 250 is identical to the Primary Predicate and substantially equivalent to the Secondary Predicates (B & C)
Location of Use (primary)	Physician's office, clinic, research center (*under supervision of physician*) and patient home environment	Physician's office, clinic, research center (*under supervision of physician*) and patient home environment	Physician's office, clinic, research center (*under supervision of physician)*	Physician's office, clinic, research center (*under supervision of physician*) and patient home environment	Physician's office, clinic, research center (*under supervision of physician*) and patient home environment	The Oscar 2, Model 250 is identical to the Primary Predicate and Secondary Predicates (B & C)

ATRIBUTE	NEW DEVICE	PRIMARY PREDICATE	SECONDARY PREDICATE (A)	SECONDARY PREDICATE (B)	SECONDARY PREDICATE (C)	COMPARISON
	SUNTECH MEDICAL INC. OSCAR 2, MODEL 250	SUNTECH MEDICAL INC. OSCAR 2, MODEL 222 (K003004)	ATCOR MEDICAL PTY LTD SPHYGMOCOR XCEL SYSTEM (K122129)	I.E.M GMBH. ABPM 7100 PWA (K140928)	MORTARA INSTRUMENTS AMBULO 2400 (K133989)	
Product Code	DXN	DXN	DXN	DXN	DXN	Identical to all predicates
System Components	• Electronics Module (Oscar 2,Model 250) • SunTech BP Cuff • Software download • Operator's Manual • Cables • Pouch	• Electronics Module (M222) • SunTech BP Cuff • Software Disc • Operator's Manual • Cables • Pouch	• Electronics Module (EM4 Hardware) • SunTech BP Cuff • Software Disc • Operator's Manual • Cables • Power Supply Adaptor	• Electronics Module (M 7100) • BP Cuff • Software Disc • Operator's Manual • Pouch	• Electronics Module (M 7100) • BP Cuff • Software Disc • Operator's Manual • Pouch	The Oscar 2, Model 250 is substantially equivalent to all predicates
Energy Used or Delivered	Mechanical Force via BP Cuff	Mechanical Force via BP Cuff	Mechanical Force via BP Cuff	Mechanical Force via BP Cuff	Mechanical Force via BP Cuff	The Oscar 2, Model 250 is identical to all predicates
Interface	USB Interface Cable Wireless - BlueTooth	Interface Cable	Interface Cable	USB Interface Cable Wireless - BlueTooth	USB Interface Cable	The Oscar 2, Model 250 is identical to the Secondary Predicate B
Mechanical Safety	Cuff Related Risks	Cuff Related Risks	Cuff Related Risks	Cuff Related Risks	Cuff Related Risks	The Oscar 2, Model 250 is identical to all predicates
Patient Connections	BP Cuff	BP Cuff	BP Cuff	BP Cuff	BP Cuff	The Oscar 2, Model 250 is identical to all predicates
Human Factors	• Ambulatory or office use with results displayed using PC Desktop interface • Graphical User Interface (GUI) on desktop interface • Use of cuff around limb • Stop button • Functional buttons • Device status Indicators	• Ambulatory or office use with results displayed using PC Desktop interface • Graphical User Interface (GUI) on desktop interface • Use of cuff around limb • Stop button • Functional Buttons • Device status Indicators	• Office use with results displayed using PC Desktop interface • Graphical User Interface (GUI) • Use of cuff around limb • Stop buttons • Functional Buttons • Device status Indicators	• Ambulatory or office use with results displayed using PC Desktop interface • Graphical User Interface (GUI) on desktop interface • Use of cuff around limb • Stop button • Functional Buttons • Device status Indicators	• Ambulatory or office use with results displayed using PC Desktop interface • Graphical User Interface (GUI) on desktop interface • Use of cuff around limb • Stop button • Functional Buttons • Device status Indicators	The Oscar 2, Model 250 is identical to the Primary Predicate and Secondary Predicates (B & C). The Oscar 2, Model 250 is substantially equivalent to the SphygmoCor XCEL with the difference that the Oscar 2, Model 250 is intended for both ambulatory or office use while the SphygmoCor XCELis intended for office use only.

ATRIBUTE	NEW DEVICE	PRIMARY PREDICATE	SECONDARY PREDICATE (A)	SECONDARY PREDICATE (B)	SECONDARY PREDICATE (C)	COMPARISON
	SUNTECH MEDICAL INC. OSCAR 2, MODEL 250	SUNTECH MEDICAL INC. OSCAR 2, MODEL 222 (K003004)	ATCOR MEDICAL PTY LTD SPHYGMOCOR XCEL SYSTEM (K122129)	I.E.M GMBH. ABPM 7100 PWA (K140928)	MORTARA INSTRUMENTS AMBULO 2400 (K133989)	
NIBP Algorithm	SunTech Oscar 2	SunTech Oscar 2	SunTech Adv. Mini OEM BP	I.E.M	Mortara	The Oscar 2, Model 250 is identical to the Primary Predicate and Secondary Predicate (A)
CBP Algorithm	SphygmoCor® XCEL	N / A	SphygmoCor® XCEL	I.E.M	N / A	The Oscar 2, Model 250 is identical to the Secondary Predicate (A
Standards Compliance	**Test to most recently Harmonized Standard**					
AAMI/IEC 60601-1 Electrical Safety & Applicable Collateral Standards	60601-1 Ed. 3.1 : 2012 & 60601-1-6 60601-1-11	YES	YES	YES	YES	The Oscar 2, Model 250 is tested to the currently effective edition, Ed. 3.1 : 2012, of the standard & applicable Collateral Standards
IEC 60601-1-2 EMC	60601-1-2:2007	YES	YES	YES	YES	The Oscar 2, Model 250 is tested to the currently effective edition, 60601-1-2:2007, of the standard
AAMI/IEC 80601-2-30	80601-2-30:2009	YES	YES	YES	YES	The Oscar 2, Model 250 is tested to the currently effective edition, 80601-2-30:2009, of the standard
ISO 81060-2	81060-2:2013	SP 10	YES	YES	YES	The Oscar 2, Model 250 is tested to the currently effective standard, 81060-2:2013.
Software Section						
User Interface	• Microsoft Windows based User Interface. • Dedicated screens for key functions. • User feedback of data quality & errors • Reporting of final results	• Microsoft Windows based User Interface. • Dedicated screens for key functions. • User feedback of data quality & errors • Reporting of final results	• Microsoft Windows based User Interface. • Dedicated screens for key functions. • User feedback of data quality & errors • Reporting of final results	• Microsoft Windows based User Interface. • Dedicated screens for key functions. • User feedback of data quality & errors • Reporting of final results	• Microsoft Windows based User Interface. • Dedicated screens for key functions. • User feedback of data quality & errors • Reporting of final results	The Oscar 2, Model 250 is identical to the Primary Predicate device and Substantially Equivalent to all Secondary Predicates

ATRIBUTE	NEW DEVICE	PRIMARY PREDICATE	SECONDARY PREDICATE (A)	SECONDARY PREDICATE (B)	SECONDARY PREDICATE (C)	COMPARISON
	SUNTECH MEDICAL INC. OSCAR 2, MODEL 250	SUNTECH MEDICAL INC. OSCAR 2, MODEL 222 (K003004)	ATCOR MEDICAL PTY LTD SPHYGMOCOR XCEL SYSTEM (K122129)	I.E.M GMBH. ABPM 7100 PWA (K140928)	MORTARA INSTRUMENTS AMBULO 2400 (K133989)	
Software Operating Platform	Microsoft Windows® 7, 8	Microsoft Windows® XP, Vista, 7, 8	Microsoft Windows® XP, Vista, 7, 8	Microsoft Windows® XP, Vista, 7	Microsoft Windows® XP, Vista, 7	The Oscar 2, Model 250 is identical to all Predicates in that it uses an MS Windows (7 & 8) platform The Oscar 2 will not be backward compatible to Windows XP and Vista
Stored Data Viewing	PC screen	PC screen	PC screen	PC screen	PC screen	The Oscar 2, Model 250 is identical to all predicates
PC Software	AccuWin Pro	AccuWin Pro	SphygmoCor	HMS-CS 4.7 CardioPerfect	Hypertension Diagnostic Suite	The Oscar 2, Model 250 is identical to the Primary Predicate and Secondary Predicate A The Oscar 2, Model 250 is substantially equivalent to Secondary Predicates B & C
SYSTEM PERFORMANCE						
Power	3 Volt Two "AA" alkaline or rechargeable batteries	3 Volt Two "AA" alkaline or rechargeable batteries	External Power 100-240 VAC, 50-60Hz Supply	3 Volt Two "AA" alkaline or rechargeable batteries	3 Volt Two "AA" alkaline or rechargeable batteries	The Oscar 2, Model 250 is identical to the Primary Predicate device and Secondary Predicates B & C
Dimensions	120 x 72 x 32 mm	120 x 72 x 32 mm	99 x 190 x 17 mm	121 x 80 x 33 mm	121 x 80 x 33 mm	The Oscar 2, Model 250 is identical to the Primary Predicate
Weight	0.28 kg	0.28 kg	Weight 0.7 kg(1.5 lbs)	0.22 kg	0.22 kg	The Oscar 2, Model 250 is identical to the Primary Predicate
Enclosure Material	ABS	ABS	Polycarbonate	unknown	unknown	Model 250 is identical to the Primary Predicate
Pressure Range	Systolic: 40 - 260 mmHg Diastolic: 25 - 200 mmHg	Systolic: 40 - 260 mmHg Diastolic: 25 - 200 mmHg	40-260 mmHg	Systolic: 60 - 290 mmHg Diastolic: 30 - 195 mmHg	Systolic: 60 - 290 mmHg Diastolic: 30 - 195 mmHg	The Oscar 2, Model 250 is identical to Primary Predicate and substantially equivalent to all Secondary Predicates

ATRIBUTE	NEW DEVICE	PRIMARY PREDICATE	SECONDARY PREDICATE (A)	SECONDARY PREDICATE (B)	SECONDARY PREDICATE (C)	COMPARISON
	SUNTECH MEDICAL INC. OSCAR 2, MODEL 250	SUNTECH MEDICAL INC. OSCAR 2, MODEL 222 (K003004)	ATCOR MEDICAL PTY LTD SPHYGMOCOR XCEL SYSTEM (K122129)	I.E.M GMBH. ABPM 7100 PWA (K140928)	MORTARA INSTRUMENTS AMBULO 2400 (K133989)	
Measurement	Determines brachial BP from oscillometric waveform pulses captured during deflation of the cuff. Derives the aortic waveform profile from the brachial artery waveform and provides a collection of pressure and timing hemodynamic parameter. The key clinical parameters are: 1. Systolic and Diastolic Blood Pressure 2. Heart Rate 3. Central Blood Pressure (Sp/Dp/MAP/Pp) 4. Central Augmentation Index & Pressure, and Index at HR 75	Determines brachial BP from oscillometric waveform pulses captured during deflation of the cuff. The key clinical parameters are: 1. Systolic and Diastolic Blood Pressure 2. Heart Rate	Determines brachial BP from oscillometric waveform pulses captured during deflation of the cuff. Derives the aortic waveform profile from the brachial artery waveform and provides a collection of pressure and timing hemodynamic parameters.. The key clinical parameters are: 1. Systolic and Diastolic Blood Pressure 2. Heart Rate 3. Central Blood Pressure (Sp/Dp/MAP/Pp) 4. Central Augmentation Index & Pressure, and Index at HR 75 5. Pulse Pressure Amplification 6. Ejection Duration 7. Subendocardial Viability Ratio 8. SphygmoCor Reference Age	Determines brachial BP from oscillometric waveform pulses captured during deflation of the cuff. Derives the aortic waveform profile from the brachial artery waveform and provides a collection of pressure and timing hemodynamic parameters. The key clinical parameters are: 1. Systolic and Diastolic Blood Pressure 2. Heart Rate 3. Central Blood Pressure (Sp/Dp/MAP/Pp) 4. Central Augmentation Index & Pressure	Determines brachial BP from oscillometric waveform pulses captured during deflation of the cuff. The key clinical parameters are: 1. Systolic and Diastolic Blood Pressure 2. Heart Rate	The Oscar 2, Model 250 is identical to all the Predicates regarding the determination of the BP signal The Oscar 2, Model 250 is identical to Secondary Predicate A and substantially equivalent to Secondary Predicate B regarding the determination of the Central BP signal The Oscar 2, Model 250 has identical measurements to both Primary and Secondary Predicate A regarding features 1 & 2 and substantially equivalent to Secondary Predicates B & C The Oscar 2, Model 250 has identical measurements to the Secondary Predicate A regarding features 3 & 4 and is substantially equivalent to Secondary Predicate B The Oscar 2, Model 250 does not use the key clinical parameters 5 – 8 found in the Secondary Predicate A.

ATRIBUTE	NEW DEVICE	PRIMARY PREDICATE	SECONDARY PREDICATE (A)	SECONDARY PREDICATE (B)	SECONDARY PREDICATE (C)	COMPARISON
	SUNTECH MEDICAL INC. OSCAR 2, MODEL 250	SUNTECH MEDICAL INC. OSCAR 2, MODEL 222 (K003004)	ATCOR MEDICAL PTY LTD SPHYGMOCOR XCEL SYSTEM (K122129)	I.E.M GMBH. ABPM 7100 PWA (K140928)	MORTARA INSTRUMENTS AMBULO 2400 (K133989)	
Method	• Capture brachial arterial waveforms non-invasively with Cuff • Apply oscillometric algorithm to captured waveforms to determine brachial BP • Brachial BP results stored for later download and display • Calibrate using Brachial BP • Single Step Measurement • Measure Brachial arterial waveform non-invasively with Cuff • Digitize peripheral arterial waveform (brachial). • Firmware applies a General Transfer Function (GTF) to peripheral waveform to derive central pressure waveform and parameters • Calculated parameters stored for later download and display	• Capture brachial arterial waveforms non-invasively with Cuff • Apply oscillometric algorithm to captured waveforms to determine brachial BP • Brachial BP results stored for later download and display	• Capture brachial arterial waveforms non-invasively with Cuff • Apply oscillometric algorithm to captured waveforms to determine brachial BP • Brachial BP results used for CBP measurement and sent to PC software • Calibrate using Brachial BP • Single Step Measurement • Measure Brachial arterial waveform non-invasively with Cuff • Digitize peripheral arterial waveform (brachial) and use serial communications to send to PC software. • PC software applies a General Transfer Function (GTF) to peripheral waveform to derive central pressure waveform and parameters	• Capture brachial arterial waveforms non-invasively with Cuff • Apply oscillometric algorithm to captured waveforms to determine brachial BP • Brachial BP results stored for later download and display • Calibrate using Brachial BP • Single Step Measurement • Measure Brachial arterial waveform non-invasively with Cuff • Digitize peripheral arterial waveform (brachial) • PC software applies a General Transfer Function (GTF) to peripheral waveform to derive central pressure waveform and parameters	• Capture brachial arterial waveforms non-invasively with Cuff • Apply oscillometric algorithm to captured waveforms to determine brachial BP • Brachial BP results stored for later download and display	The Oscar 2, Model 250 is substantially the same regarding measurements methods to both Primary and Secondary Predicate (A)

(7) Testing and Validations

The Oscar 2, Model 250 has been tested to the applicable requirements of the following standards and requirements documents. These tests have indicated passing results.

- IEC 60601-1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.
- IEC 60601-1-6:2013, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-11:2012, Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance –Collateral Standard: Requirements for medical electrical
- IEC 80601-2-30:2013, Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- ISO 81060-2:2013, Non-invasive sphygmomanometers —Part 2: Clinical investigation of automated measurement type

(8) Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, SunTech Medical concludes that the Oscar 2, Model 250 is substantially equivalent to the predicate devices described herein.