MAR 0 4 2014

510(k) Summary of Safety and Effectiveness in accordance with 21 CFR 807.92

(a) (1) **Submitted by:**

HealthSTATS International Pte. Ltd.
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Contact Person: Dr. Choon Meng TING
Position/Title: Chairman/CEO

Date of Preparation: May 31, 2013

Trade Name: HealthSTATS A-PULSE CASPal®+and MC3100™+ Monitors and my-BP™ BP Management Application Software

Common/Classification Name: System, Measurement, Blood-pressure, Non-invasive

Product Code: 74 DXN, 21 CFR § 870.1130

Class: Class II

(3) **Predicate Device(s):**

K101002	HealthSTATS A-PULSE CASPal® , HealthSTATS International Pte Ltd.
K040371	A&D Medical UA767BT Blood pressure monitor, A&D Engineering, Inc.
K061822	Omron Health Management Software (accessory PC software to Omron HEM-780, Omron Healthcare Ltd.

Reason for Submission: New Device

(4) **Description of Device:**

The HealthSTATS A-PULSE CASPal®+ and MC3100™+ are standalone noninvasive blood pressure monitors which are designed to measure (1) conventional oscillometric blood pressure with a brachial cuff and (2)

Central Aortic Systolic Pressure (CASP) and other indices based on arterial tonometry at the radial artery of the wrist.

The CASPal®+ Monitor is comprised of four main elements:

- System embedded processing unit.
- Integrated oscillometric blood pressure module for calibration (identical to the BPCalibrator [listed device **K041546**], also cleared iin CASPal device **K101002**).
- Wrist sensor module for acquistion of central aortic systolic pressure (CASP) via radial arterial tonometry at the wrist [cleared accessory and method **K101002**].
- Bluetooth® wireless communications module.

The MC3100™+ is a reduced feature set of the CASPal®+ which only offers the oscillometric blood pressure measurement and not the CASP measurement, but is otherwise identical. my-BP™ PC software may be used with either device to store and display blood pressure and pulse rate measurements on a suitably equipped computer.

(5) **Intended use:**

The A-PULSE CASPal®+ and MC3100™+ Monitors are intended to measure systolic and diastolic blood pressure and pulse rate via the oscillometric method with cuff. The A-PULSE CASPal®+ utilizes a wrist sensor to obtain the radial pulse waveform to derive central aortic systolic pressure (CASP) and other waveform indices. Both monitors utilize Bluetooth wireless technology to transfer measurements to HealthSTATS my-BP™ PC Software or other suitable devices.

Cardiovascular disease remains among the leading causes of death worldwide. Hypertension assessment is one of the primary factors in the evaluation of cardiovascular disease. Assessment of CASP may improve the management of patients with elevated cardiovascular risk.

Indications for Use:

The A-PULSE CASPal+ Monitor is a compact standalone monitor that combines two methods of blood pressure measurement:

- Conventional oscillometric blood pressure via a brachial cuff on the upper arm, and
- Radial arterial pulse acquisition via a wrist-mounted tonometer sensor.

The A-PULSE CASPal+ Monitor first measures systolic and diastolic blood pressure and pulse rate using the oscillometric method, and then acquires the radial arterial pulse waveform to derive the **C**entral **A**ortic **S**ystolic **P**ressure (CASP) non-invasively.

The MC3100+ monitor measures systolic and diastolic blood pressure and pulse rate via the oscillometric method via a brachial cuff at the upper arm.

The monitors have a non-volatile memory to store and recall measurements, and the ability to transfer measurement data via Bluetooth wireless communications to other suitably equipped electronic devices, such as a PC with HealthSTATS my-BP PC software.

my-BP PC software is used in conjunction with the HealthSTATS A-PULSE CASPal+ and MC3100+ Monitors to store and display blood pressure data obtained from the monitors.

The A-PULSE CASPal+ and MC3100+ Monitors are intended for use on patients who are eighteen (18) years and older, and for the CASPal+, have a palpable radial pulse.

Brachial Blood pressure, CASP and pulse rate readings obtained using the A-PULSE CASPal+ and MC3100+ Monitors are intended for use by qualified healthcare personnel as an aid to diagnosis and treatment.

(6) **Technological Characteristics:**

Two monitors are offered in this 510(k), the A-PULSE CASPal®+ Monitor and the MC3100™+:

- The A-PULSE CASPal®+ Monitor measures and displays blood pressure readings with a pulse bar to display radial arterial pulsations. The device measures both oscillometric blood pressure via a brachial cuff and Central Aortic Systolic Pressure (CASP) via a wrist-mounted tonometer sensor. The A-PULSE CASPal®+ is substantially identical to the predicate A-PULSE CASPal monitor except that the CASPal®+ is capable of Bluetooth® wireless data transmission of measurements.
- The MC3100™+ Monitor offers a reduced feature set of the CASPal®+ and measures only oscillometric blood pressure via a brachial cuff. The MC3100™+ also is capable of Bluetooth® wireless data transmission.

My-BP™ PC Software is a software application which, when loaded on a computer suitably equipped with Bluetooth® functionality, is able to acquire measurement data from CASPal®+ and MC3100™+ for subsequent storage and display.

(b) (1) **Non-Clinical Tests Submitted:**

The A-PULSE CASPal®+/MC3100™+ Monitors have been tested to meet applicable standards for medical device electrical safety, electromagnetic

compatibility, environmental (temperature and humidity), and mechanical strength (shock and vibration).

Materials utilized in skin contact surfaces are in accessories cleared for the same intended use. The materials met biocompatibility requirements.

The embedded software of the A-PULSE CASPal®+/MC3100™+ Monitors has been verified to requirements and validated to meet intended use. HealthSTATS my-BP™ PC Software has been verified to meet specified requirements for the storage and display of retrospective vital blood pressure and pulse rate data.

System level risk, hazard, and failure mode analysis has been performed on both hardware and software, and residual risks were determined to be acceptable.

(2) **Clinical Tests Submitted:**

Clinical testing performed on the cleared predicate A-PULSE CASPal device, which is functionally and physically identical to the A-PULSE CASPal®+ device except for the addition of the Bluetooth® wireless data transmission, was determined to be applicable to the CASPal®+ and MC3100™+ monitors. Therefore no new clinical data was submitted.

(3) **Conclusions from Tests:**

As described in (b)(1) and (b)(2) above, the testing demonstrates that the A-PULSE CASPal®+/MC3100™+ Monitors and my-BP™ PC Software are as safe and effective as, and function in a manner equivalent to the referenced predicate devices.

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

March 4, 2014

Healthstats International Pte. Ltd.
Stephen Gorski
S65 W35739 Piper Road
Eagle, WI 53119 US

Re: K131788

Trade/Device Name: Trade/Device Name: HealthSTATS A-PULSE CASPal®+ and MC3100™+ Monitors and my-BP™ BP management application software

Regulation Number: 21 CFR 870.1130
Regulation Name: System, Management, Blood-Pressure, Non-Invasive
Regulatory Class: Class II
Product Code: DXN
Dated: January 22, 2014
Received: January 27, 2014

Dear Stephen Gorski:

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,

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

Enclosure

K131788

Indications for Use

510(k) Number (if known):

Device Name: HealthSTATS A-PULSE CASPal®+ and MC3100™+ Monitors and my-BP™ BP Management Application Software

Indications for use:

The A-PULSE CASPal+ Monitor is a compact standalone monitor that combines two methods of blood pressure measurement:

- Conventional oscillometric blood pressure via a brachial cuff on the upper arm, and
- Radial arterial pulse acquisition via a wrist-mounted tonometer sensor.

The A-PULSE CASPal+ Monitor first measures systolic and diastolic blood pressure and pulse rate using the oscillometric method, and then acquires the radial arterial pulse waveform to derive the **C**entral **A**ortic **S**ystolic **P**ressure (CASP) non-invasively.

The MC3100+ monitor measures systolic and diastolic blood pressure and pulse rate via the oscillometric method via a brachial cuff at the upper arm.

The monitors have a non-volatile memory to store and recall measurements, and the ability to transfer measurement data via Bluetooth wireless communications to other suitably equipped electronic devices, such as a PC with HealthSTATS.my-BP PC software.

my-BP PC software is used in conjunction with the HealthSTATS A-PULSE CASPal+ and MC3100+ Monitors to store and display blood pressure data obtained from the monitors.

The A-PULSE CASPal+ and MC3100+ Monitors are intended for use on patients who are eighteen (18) years and older, and for the CASPal+, have a palpable radial pulse.

Brachial Blood pressure, CASP and pulse rate readings obtained using the A-PULSE CASPal+ and MC3100+ Monitors are intended for use by qualified healthcare personnel as an aid to diagnosis and treatment.

Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician or other licensed practitioner.

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

Date: 2014.03.04 15:57:04 -05'00'

for Bram Zuckerman