

K101002

**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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E-mail: cmting@healthstats.com.sg
- Contact Person:** Dr. Choon Meng TING  
**Position/Title:** Chairman/CEO
- Date of Preparation:** August 1, 2009
- Trade Name:** HealthSTATS A-PULSE CASPro/CASPal Monitors
- Common/Classification Name:** System, Measurement, Blood-pressure, Non-invasive
- Product Code:** 74 DXN, 21 CFR § 870.1130
- Class:** Class II
- (3) **Predicate Device(s):**
- |         |  |
|---------|--|
| K072593 | HealthSTATS A-Pulse® Arterial Pulse Waveform Analysis System, HealthSTATS International Pte Ltd  |
| K060315 | HealthSTATS BPro® Ambulatory Blood Pressure Monitoring System, HealthSTATS International Pte Ltd |
| K051546 | HealthSTATS BPCalibrator MC300/MC3100 Blood Pressure Monitor, HealthSTATS International Pte Ltd  |
| K012487 | SphygmoCor Pulse Waveform Analysis System, AtCor Medical Pty Ltd                                 |
- Reason for Submission:** New Device
- (4) **Description of Device:**
- HealthSTATS A-PULSE CASPro/CASPal Monitors 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 CASPro/CASPal Monitors are comprised of four main elements:

- Integrated oscillometric blood pressure module for calibration (identical to the BPCalibrator [listed device **K041546**]).
- Wrist sensor module based on the technology of the BPro® monitor device [listed device **K060315**].
- Software algorithm for radial arterial blood pressure measurement and calculation of CASP based on the A-PULSE PC Software [listed device **K072593**].
- A-PULSE CASPro®, A-PULSE CASPal® main processing unit.

(5) **Intended use:**

The A-PULSE CASPro/CASPal Monitors are intended to measure systolic and diastolic blood pressure and pulse rate, and to utilize the radial pulse waveform to derive central aortic systolic pressure (CASP) and other waveform indices.

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 stratification and management of patients with elevated cardiovascular risk.

**Indications for Use:**

The A-PULSE CASPro/CASPal Monitors are compact standalone monitors that combine 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 CASPro/CASPal Monitors first measure systolic and diastolic blood pressure and pulse rate via the oscillometric method, and then acquire the radial arterial pulse waveform to derive the Central Aortic Systolic Pressure (CASP) non-invasively.

The A-PULSE CASPro monitor has a graphical display that displays the arterial pulse waveform as well as a range of other pulse indices. The A-PULSE CASPal monitor has a numeric display. Both models have a non-volatile memory to store and recall measurements.

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

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

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

**(6) Technological Characteristics:**

Two functionally equivalent monitors are offered in this 510(k), the A-PULSE CASPro Monitor and the A-PULSE CASPal Monitor:

- The CASPro Monitor device is equipped with a full featured color TFT LCD panel to display blood pressure readings and radial arterial pulse waveforms. The device also has a real time calendar clock for time-stamped stored readings.
- The A-PULSE CASPal Monitor device is equipped with a simplified monochrome LCD panel to provide numeric blood pressure readings and a pulse bar to display radial arterial pulsations.

The operation sequence of both A-PULSE CASPro and CASPal Monitors is the same and both devices use identical hardware and software algorithms to measure and report conventional systolic and diastolic blood pressure readings (BP), Central Aortic Systolic Pressure (CASP), and pulse rate (PR).

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

The A-PULSE CASPro/CASPal Monitor has been tested to meet applicable standards for medical device electrical safety, electromagnetic compatibility, shock and vibration, and environment (temperature and humidity), as well as specific compliance requirements for blood pressure monitors.

Materials utilized in skin contact surfaces were reviewed for conformance with biocompatibility requirements. The materials met the requirements.

The embedded software of the A-PULSE CASPro/CASPal Monitors has been verified to requirements and validated to meet intended use. System level risk, hazard, and failure mode analysis has been performed and residual risks were determined to be acceptable.

**(2) Clinical Tests Submitted:**

The A-PULSE CASPro/CASPal Monitors were clinically tested in comparison with listed devices for the measurement of central aortic systolic pressure (CASP). Test results demonstrate CASP measurements that are consistent with the predicate devices within the stated accuracy claims.

**(3) Conclusions from Tests:**

As described in (b)(1) and (b)(2) above, the testing demonstrates that the A-PULSE CASPro/CASPal Monitors are as safe and effective as, and function in a manner equivalent to the predicate devices.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room W-O66-0609  
Silver Spring, MD 20993-0002

JUN - 8 2010

HealthSTATS International Pte., Ltd.,  
c/o Mr. Stephen Gorski  
Imagenix, Inc.  
S65 W35739 Piper Road  
Eagle, WI 53119

Re: K101002  
Trade/Device Name: A-PULSE CASPro® and A-PULSE CASPal® Monitors  
Regulatory Number: 21 CFR 870.1130  
Regulation Name: Non-invasive Blood Pressure Measurement System  
Regulatory Class: II (two)  
Product Code: DXN  
Dated: March 5, 2010  
Received: April 12, 2010

Dear Mr. 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.

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.

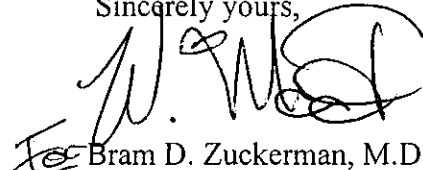
Page 2 – Mr. Stephan Gorski

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,



~~To~~ Bram D. Zuckerman, M.D.

Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K 101002

Device Name: HealthSTATS A-PULSE CASPro/CASPal Monitors

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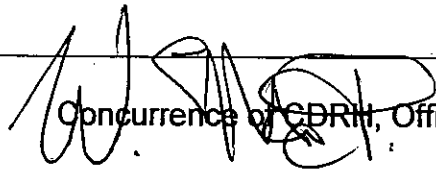
Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician or other licensed practitioner.

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)

(Division Sign-Off)  
Division of Cardiovascular Devices

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