K072593

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

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

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NOV 1 5 2007

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Contact Person: Dr. Ting Choon Meng, M.D.

Position/Title: CEO

Date of Preparation: September 13, 2007

Trade Name: HealthSTATS A-Pulse™ Arterial Pulse Waveform Analysis System

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

Product Code: 74 DXN, 21 CFR § 870.1130

Class: Class II

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

K060315	HealthSTATS BPro® Ambulatory Blood Pressure Monitoring System, HealthSTATS International Pte Ltd
K012487	SphygmoCor Pulse Waveform Analysis System, AtCor Medical Pty Ltd
K050233	Omron HEM 9000AI Non-invasive Blood Pressure Monitor with Augmentation Index, Omron Healthcare Inc.

Reason for Submission: New Device

(4) **Description of Device:**

HealthSTATS BPro® is a noninvasive arterial waveform analysis system system based on arterial tonometry at the radial artery of the wrist. The system consists of three main elements:

- A-Pulse PC Software for radial arterial pulse waveform analysis, a PC-based computer program [new device].

- BPro® wrist-mounted tonometric monitor [listed device K060315].
- BPCalibrator MC3000 oscillometric blood pressure monitor [listed device, K051546] for calibration of the BPro monitor..

Once calibrated using the BPCalibrator oscillometric device, A-Pulse PC Software is capable of acquiring and displaying arterial blood pressure waveforms from the BPro wrist device.

(5) **Intended use:**

Blood pressure is measured in millimeters of mercury (mmHg) and is represented by two values: systolic pressure and diastolic pressure. The systolic pressure represents the pressure in the blood vessels when the heart contracts (pumps), while the diastolic pressure is the pressure when the heart relaxes and blood fills the heart. The two pressures are clinically useful, however they do not fully describe the dynamics of the heart's pumping.

Arterial pulse waveform analysis can provide additional information on the condition of the heart and the arterial tree. The shape of the arterial pulse waveform can be interpreted to assist with diagnosis of specific cardiovascular conditions.

Indications for Use:

The A-Pulse^{TM} Arterial Pulse Waveform Analysis System consists of A-Pulse PC Software, the BPro® Blood Pressure monitor, and the BPCalibrator Oscillometric monitor.

A-Pulse PC software is used in conjunction with the HealthSTATS BPro Blood Pressure monitor to provide data to qualified medical personnel for the purpose of assessing the patient's cardiac health via blood pressure waveforms measured at the radial artery.

Before each measurement session, the BPro wrist-mounted tonometric device is calibrated using the BPCalibrator oscillometric monitor. Once calibrated, A-Pulse PC Software is capable of acquiring and displaying arterial blood pressure waveforms from the BPro wrist device.

A-Pulse PC software is intended to measure systolic and diastolic blood pressure and pulse rate, and to utilize the radial pulse waveform to derive central aortic pressure (CAP), radial augmentation index (rAI), and a range of other indices.

A-Pulse PC Software is 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:**

The A-Pulse™ Arterial Pulse Waveform Analysis System measures and records radial arterial waveforms and derives two indices which are also reported by the combination of referenced predicate devices:

- Radial Augmentation Index (rAI)
- Central Aortic Pressure (CAP*).

The BPro monitor is applied to the wrist with a pressure transducer placed over the radial artery. The monitor has a size and weight similar to a sports type wrist watch. An embedded microcontroller supervises the actions of the monitor including scheduled measurements, on-demand measurements, and serial data communication with the host PC.

The A-Pulse PC Software measures arterial waveforms in real time, calculates blood pressure parameters and indices on selected waveforms, and stores and prints reports.

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

The BPro monitor devices meet applicable standards for medical device electrical safety, electromagnetic compatibility, shock and vibration, and environment (temperature and humidity).

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

The A-Pulse PC software was verified to requirements and validated to meet intended use. System level risk and failure mode analysis was performed and residual risks were determined to be acceptable.

(2) **Clinical Tests Submitted:**

The A-Pulse Arterial Pulse Waveform Analysis System was clinically tested in comparison with the listed devices for the derivation of the indices. Test results confirm reliable indices that are consistent with the predicate device measurements 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 Arterial Pulse Waveform Analysis System is as safe and effective as, and functions in a manner equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2007

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

Re: K072593
A-Pulse Arterial Waveform Analysis System, A-Pulse System 7000, and
A-Pulse Arterial Pulse PC Software, A-Pulse 7000
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: June 5, 2007
Received: September 14, 2007

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman 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

510(k) Number (if known): K072593

Device Name: HealthSTATS A-Pulse™ Arterial Pulse Waveform Analysis System

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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)

B Runnion

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K072593