

K060315

APR 7 2006

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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. Ting Choon Meng, M.D.

Position/Title: President/CEO

Date of Preparation: February 4, 2006

Trade Name: HealthSTATS BPro® Ambulatory Blood Pressure Monitoring 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):**

K900247 CBM-3000/CBM-2000/CBM-7000 Blood Pressure System, Colin Medical Instruments Corp.

K855127 Ambulatory Blood Pressure Monitor #90202, Spacelabs, Inc.

K031479 Ambulatory Blood Pressure (ABP) 92506 Report Management System, (Spacelabs) Datex-Ohmeda, Inc.

Reason for Submission: New Device

(4) **Description of Device:**

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

- BPro/BPal wrist-mounted tonometric monitor.

- BProSoft report management software, a PC-based computer program.
- BPCalibrator MC3000 oscillometric blood pressure monitor [listed device, K051546] for calibration of BPro/BPal monitors.

Once the BPro is calibrated using the BPCalibrator oscillometric device, it is capable of measuring and recording systolic pressure, diastolic pressure and pulse rate over a period of 24 hours.

(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.

Blood pressure fluctuates throughout the day. Specific ranges are associated with normal, hyper- and hypotension. Ambulatory blood pressure measurement devices provide useful 24 hour blood pressure profiles. Evaluation of the profiles can assist with diagnosis of specific cardiovascular conditions.

Indications for Use:

The BPro® system is a noninvasive ambulatory blood pressure monitoring system based on arterial tonometry at the radial artery of the wrist. The system consists of a BPro wrist-mounted tonometric monitor, a BPCalibrator MC3000 oscillometric blood pressure monitor for calibration, and BProSoft software, a PC-based computer program.

Before each measurement session, the wrist device is calibrated using the oscillometric monitor. Once calibrated, the BPro wrist device is capable of recording and displaying up to 96 measurements of systolic and diastolic blood pressure and pulse rate over a period of 24 hours.

BProSoft PC software is used to provide data to qualified medical personnel for the purpose of assessing the patient's cardiac health via blood pressure readings taken during daily activity for up to a 24-hour period.

The BPro system is intended for use on patients who are eighteen (18) years and older and who have a palpable radial pulse.

The BPro system is intended only for measurement, recording, and display. It makes no diagnosis.

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 BPro Ambulatory Blood Pressure Monitoring System combines two established measurement methods used by the referenced predicate devices:

- Blood pressure measurement at the wrist using arterial tonometry
- Oscillometric blood pressure measurement for calibration.

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 data storage of up to 96 systolic/diastolic/pulse rate readings in a 24 hour period.

The BPro monitor is battery operated and utilizes an LCD for display of the measurements. The BPro is capable of serial communication via an RS-232 port to upload ambulatory data to the BProSoft PC Report management software application. The BPal monitor is a reduced feature version of the BPro which does not support the serial data transmission.

The BPro/BPal devices measure a similar range of blood pressures as the predicate devices.

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

The BPro monitor devices were tested in accordance with applicable standards for medical device electrical safety, electromagnetic compatibility, shock and vibration, and environment (temperature and humidity). The devices passed the tests.

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

System level tests of the BPro monitor included measurement accuracy, intra-device variability, life, and extended range bench testing. The devices tested satisfied performance criteria.

The BPro monitor embedded software and BProSoft PC software were verified to requirements and validated to meet intended use. Risk and failure mode analysis was performed and residual risks were determined to be acceptable.

(2) **Clinical Tests Submitted:**

The BPro Ambulatory Blood Pressure Monitoring System was clinically tested in accordance with AAMI-SP10, Electronic or Automated Sphygmomanometers. The requirements of the standard were met for stationary tests and the recommendations of the standard were met for ambulatory tests.

(3) **Conclusions from Tests:**

As described in (b)(1) and (b)(2) above, the testing demonstrates that the BPro® Ambulatory Blood Pressure Monitoring System is as safe and effective as, and functions in a manner equivalent to the predicate devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2006

HealthSTATS International Pte. Ltd.
c/o Ting Choon Meng, MD
President/CEO
6 New Industrial Road #04-01/02
Hoe Huat Industrial Building
SINGAPORE 536199

Re: K060315

Trade Name: HealthSTATS BPro[®] Ambulatory Blood Pressure Monitoring System
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: October 25, 2005
Received: February 08, 2006

Dear Mr. Meng:

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.

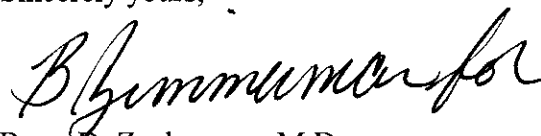
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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" (21 CFR 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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): K060315

Device Name: HealthSTATS BPro[®] Ambulatory Blood Pressure Monitoring System

Indications for use:

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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)



(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060315