June 21, 2018

HealthSTATS International Pte. Ltd.
% Stephen Gorski
President
Imagenix, Inc.
S65 W35739 Piper Road
Eagle, Wisconsin 53119

Re: K173028
Trade/Device Name: BPro BT Ambulatory Blood Pressure Monitoring System with BProSoft BT PC Software
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 22, 2018
Received: May 23, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*

K173028

Device Name
HealthSTATS BPro® BT Ambulatory Blood Pressure Monitoring System with BProSOft BT PC Software

Indications for Use *(Describe)*

The BPro® BT Ambulatory Blood Pressure Monitoring 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 BT wrist-mounted tonometric monitor, a BPCalibrator MC3100+ oscillometric blood pressure monitor for calibration, and BProSOft BT 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 BT 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 BT system is intended for use on patients who are eighteen (18) years and older and who have a palpable radial pulse.

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

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

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

HealthSTATS International Pte. Ltd.
6 New Industrial Road #04-01/02
Singapore 536199

Phone: +65-6858 3248
Fax: +65-6858 0148

E-mail: cmting@healthstats.com.sg

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

Position/Title: President/CEO

Date of Preparation: June 20, 2013

Trade Name: HealthSTATS BPro® BT Ambulatory Blood Pressure Monitoring System with BProSOft BT PC software

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

Product Code: 74 DXN, 21 CFR § 870.1130

Class: Class II

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

K060315 BPro Ambulatory Blood Pressure Monitoring with BProSOft application software

Reason for Submission: Device Modification (SPECIAL 510(k))

(4) **Description of Device:**

HealthSTATS BPro® BT Ambulatory Blood Pressure Monitoring System with BProSOft PC software 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 BT wrist-mounted tonometric monitor.
- BProSoft BT report management software, a PC-based computer program.

- BPCalibrator MC3100+ oscillometric blood pressure monitor [listed device, **K131788**] for calibration of BPro BT monitor.

Once the BPro BT 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. Blood pressure measurements obtained over the 24 hour period are transferred wirelessly by the BProSoft BT PC software for storage, display, and reports.

(5) **Intended use:**

Blood pressure is measured in millimeters of mercury (mmHg) and is typically 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 This submission includes the addition of ambulatory central aortic systolic pressure measurement. Evaluation of blood pressure profiles can assist with diagnosis of specific cardiovascular conditions.

Indications for Use:

The BPro® BT Ambulatory Blood Pressure Monitoring 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 BT wrist-mounted tonometric monitor, a BPCalibrator MC3100+ oscillometric blood pressure monitor for calibration, and BProSOft BT 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 BT 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 BT system is intended for use on patients who are eighteen (18) years and older and who have a palpable radial pulse.

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

Prescription device.

(6) **Technological Characteristics:**

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

- BPro ambulatory blood pressure monitoring at the wrist using arterial tonometry
- Arterial pulse waveform analysis to determine the CASP.

The BPro BT 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.

The scope of the modifications in this 510(k) are described below:

- Add wireless Bluetooth data transmission function to the BPro wrist applied blood pressure monitor to permit wireless data transfer to/from the monitor;
- Upgrade the display of the BPro wrist worn blood pressure monitor from black/white to color to provide an improved user interface;
- A rechargeable Li-Ion battery replaces the disposable coin cell battery; and
- Update the BProSOft PC software with modifications to support wireless data interchange.

An embedded microcontroller supervises the actions of the monitor including scheduled measurements, status reporting, and wireless data communications with the host PC. No modifications to the blood pressure hardware sensor or software algorithms were made with this device modification.

The BProSOft BT PC software acquires ambulatory blood pressure data from the BPro BT Monitor – the device's capabilities have been expanded to included Bluetooth wireless data transfer.

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

The BPro BT monitor device has been tested to 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 BProSOft BT PC software was verified to requirements and validated to meet intended use. System level risk, hazard, and failure mode analysis was performed and residual risks were determined to be acceptable.

(2) **Clinical Tests Submitted:**

No clinical tests have been submitted – the blood pressure measurement is unaffected by the device modification, which is limited to the device display change to color, wireless data transmission of blood pressure records, and the addition of an internal rechargeable battery.

(3) **Conclusions from Tests:**

As described in (b)(1) and (b)(2) above, HealthSTATS BPro® BT Ambulatory Blood Pressure Monitoring System with BProSOft BT PC Software is equivalent to the predicate as supported by compliance, laboratory, and bench testing.

The results of all tests demonstrate that the HealthSTATS BPro® BT Ambulatory Blood Pressure Monitoring System with BProSOft BT PC software meets specified requirements for device compatibility and substantial equivalence to the referenced predicate devices.