K121266
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510 (k) Summary

DEC 11 2012

Date Prepared:	November 28, 2012
Sponsor Information:	Pulsecor Limited Level 2, 135 Morrin Road Auckland 1072, New Zealand
Sponsor Contact:	Andrew Lowe Telephone: 64 (9) 280 3504 Fax: 64 (9) 280 3505
Device Name:	CardioScope™
Common/Usual Name:	NIBP
Classification Name:	Noninvasive Blood Pressure Measurement System
Regulation Number:	21 CFR 870.1130
Product Code:	DXN
Device Classification:	Class II
Review Panel:	Division of Cardiovascular Devices

1. Predicate Devices

Manufacturer	Brand Name	510(k) Number
HealthSTATS International Pte Ltd.	A-PULSE CASPro and A-PULSE CASPal Monitors	K101002
AtCor Medical Pty Ltd.	SphygmoCor Px	K012487
I.E.M. GmbH	Mobil-O-Graph 24h PWA and Hypertension Management Software Client Server	K110603

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2. Product Description

The CardioScope™ is a compact standalone measurement device that incorporates a SP10 compliant conventional oscillometric blood pressure module using a brachial cuff on the upper arm.

The CardioScope first measures brachial systolic and diastolic blood pressures and pulse rate using the Oscillometric method. It then inflates the cuff to a pressure about 30 mmHg higher than systolic (Suprasystolic) pressure to acquire a further oscillometric pulse waveform. The suprasystolic pulse waveform is used in combination with the conventional upper-arm blood pressures to derive central systolic, diastolic and mean blood pressures.

3. Indications for Use

CardioScope™ is a non-invasive, compact standalone measurement device that automatically measures systolic and diastolic pressure, and pulse rate in adult and pediatric patients. CardioScope also provides non-invasive central (aortic) systolic, mean and diastolic blood pressure, and pulse waveform intended for use in adult patients.

CardioScope performs measurements using a conventional oscillometric method via a brachial cuff on the upper arm.

The device is intended to be used under supervision by qualified healthcare personnel.

Caution: Federal (USA) law restricts this device to sale by or on order of a physician.

4. Predicate Product Comparisons

Table 12.1 compares the predicate devices with the Pulsecor CardioScope™ as it relates to indications for use, Blood pressure measurements, pulse rate, pulse waveforms, central systolic pressure, blood pressure cuff and operating temperature and humidity, storage requirements, power source and product dimensions.

All of the parameters used to compare the various areas of interest were substantially equivalent with one exception:

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Parameters	Pulsecor CardioScope™	HealthSTATS A-Pulse CASPro	AtCor SphygmoCor Px	I.E.M GmbH Mobil-O-Graph 24h
Pulse Waveform	Brachial pulse waveform using oscillometry	Radial pulse wave form using applanation tonometry	Carotid or radial pulse wave form using applanation tonometry	Brachial pulse waveform using oscillometry

A discussion of the applanation tonometry method versus the oscillometry method was presented with the conclusion that no new issues of safety and effectiveness were found between the two methods.

5. Safety and Effectiveness Studies

5.1 Summary Electrical Testing

Standard	Results
IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.	Pass
IEC 60601-1-2: 2007 Medical Electrical Equipment – Part 2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility	Complies

5.2 Summary Biocompatibility Tests - WelchAllyn FlexiPort Cuff (K070060)

Standard	Results
ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity	The test article is considered non-cytotoxic and meets the requirements of the Elution Test, ISO 10993.
ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	The Primary Irritation Index is 0.0, and the test article is considered a non-irritant according to the procedures outlined in the FHSA guidelines, 16 CFR, Section 1500.41.
ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	The skin treated with the test article extract exhibited no reaction to the challenge (0% sensitization). Therefore, as defined by the scoring system of Kligman, this is a Grade I reaction and the test article extract is

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	classified as having weak allergenic potential. A Grade I sensitization rate is not considered significant.

Summary SP10 Tests

Standard	Results
ANSI/AMMI SP10:2002	The Noninvasive software algorithm meets the ANSI/AAMI SP10:2002 requirements for adults/pediatrics

5.3 Clinical Validation (Comparison) Study Summary

Bland-Altman analysis of agreement between tonometric and oscillometric estimation of central systolic, diastolic, and mean pressures showed mean differences of less than 5 mmHg, and standard deviations of the difference of less than 8 mmHg. Similarly, agreement between oscillometric measures and invasive (catheter) measures of central systolic, diastolic, and mean pressures showed mean differences of less than 5 mmHg, and standard deviations of the difference of less than 8 mmHg.

6. Conclusion

The Pulsecor CardioScope™ has demonstrated it is substantially equivalent to the predicate devices listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

DEC 11 2012

Pulsecor, Ltd.
c/o Mr. E.J. Smith
President
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

Re: K121266
Trade/Device Name: Cardioscope
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: November 28, 2012
Received: November 28, 2012

Dear Mr. Smith:

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.

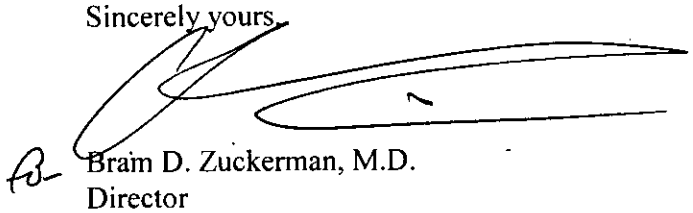
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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,



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

Enclosure

Indications for Use Form

510(k) Number (if known): K121266

Device Name: CardioScope

Indications for Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121266