moor instruments
laser Doppler blood flow assessment

K102433

moorVMS-PRES Pressure Cuff Controller
510(k) Summary

NOV 18 2010

Submitter:	Moor Instruments Ltd
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Contact:	Xiabing Huang
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Date:	August 25th, 2010
Model Name:	moorVMS-PRES Pressure Cuff Controller
Model Number:	moorVMS-PRES
Common Name:	Pressure Cuff Controller
Classification Name:	Air Plethysmograph / Pulse Volume Recorder, DPW, 21 CFR
Regulatory Status:	Class II
Establishment Reg No:	8043564
Type of 510(k):	Traditional
Reason for submission:	New device
Predicate Device:	PF 5050 Pressure Unit, Perimed AB. 510(k) Number K011899

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Description of the Device

The moorVMS-PRES vascular assessment pressure cuff controller is a device for cuff inflation and deflation control and pressure measurement. It allows connection of a range of standard pressure cuffs, ranging in size from small digit cuffs to leg cuffs. It incorporates an air pump for cuff inflation and a proportional valve for controlled deflation. The moorVMS-PRES provides measurement of cuff gauge pressure which can be displayed on the front panel, and also the AC component of the cuff pressure (referred to as pulse volume) which can be outputted as analogue signals via a BNC connector or as digital data via the USB port.

The moorVMS-PRES is capable of performing timed inflation/deflation sequences when used alone and also be capable of remote control when connected to a PC via USB.

The moorVMS-PRES is intended to form part of a modular vascular monitoring system when used in conjunction with the moorVMS-LDF laser Doppler perfusion and temperature monitors. When used in this way the instruments will be controlled and monitored via USB using PC software to perform vascular assessment such as Skin Perfusion Pressure (SPP), Limb Blood Pressure or Toe Blood Pressure (LBP/TBP), Pulse Volume (PV), and Post Occlusive Reactive Hyperemia (PORH) analyses. The moorVMS-LDF laser Doppler perfusion and temperature monitor has FDA 510(k) approval K083082.

Intended Use

The moorVMS-PRES pressure cuff controller is a device for cuff inflation and deflation control and pressure measurement. It is intended to allow non-invasive measurement of skin perfusion pressure, pulse volume, systolic blood pressure and ankle/toe brachial pressure index when used with a laser Doppler monitor either manually by the operator or automatically by separate dedicated PC software.

Comparison to Predicate Device

Technological Characteristics

Both moorVMS-PRES and the predicate device PF 5050 control cuff pressure and measure cuff pressure and PV pressure oscillations. Both are intended for use with PC software for PV analysis and also for PORH, SPP and LDP/TBP analyses when a laser Doppler blood flow monitor is connected.

Both devices rely on the same principles of operation, i.e. a piezoelectric pressure sensor for both pressure and AC pulse volume measurement. The moorVMS-PRES and the predicate device both control cuff pressure. The difference is that the predicate device uses a manual pump for inflation while the moorVMS-PRES controls both cuff inflation and cuff deflation automatically. The performance of the moorVMS-PRES is equivalent to or greater than that of the predicate device in terms of accuracy, inflation and deflation.

The moorVMS-PRES has the same levels of biocompatibility, sterilization and electrical safety as the predicate device PF 5050 Pressure Unit. The moorVMS-PRES pressure safety is equivalent to or greater than that of the predicate device.

Both devices have pressure control protocols for PV, PORH, SPP and LBP/TBP analyses performed by the PC program. The moorVMS-PRES also allows users to build pressure control protocols from the stages used in the analyses. Further more the moorVMS PC software provides Ankle Brachial Pressure Index (ABPI) and Toe Brachial Pressure Index (TBPI) calculation based on the limb and toe systolic blood pressure measured.

Performance Standards

The moorVMS-PRES has been designed and tested for compliance with the following standards:

- IEC 60601-1:2005 Medical Electrical Equipment General Requirements for basic safety and essential performance including corrigendum 1 Dec 2006.
- IEC 60601-1-2:2007 Medical electrical equipment. Collateral standard. Electromagnetic compatibility. Requirements and tests
- IEC 60601-1-6:2006 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ISO 10993-1:2003 Biological evaluation of medical devices - Part 1: Evaluation and testing

Conclusions

From the description of the technological characteristics and the performance standards above, it can be concluded that the moorVMS-PRES is substantially equivalent to the Perimed PF5050 predicate device, in terms of effectiveness and safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Moor Instruments LTD
c/o Mr. Xiabing Huang
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NOV 18 2010

Re: K102433
Trade/Device Name: moorVMS-PRES Pressure Cuff Controller
Regulatory Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: II (two)
Product Code: DPW
Dated: August 24, 2010
Received: August 26, 2010

Dear Mr. Huang:

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.

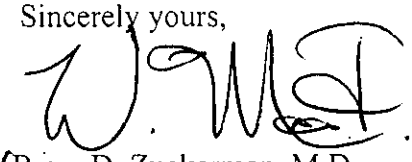
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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,



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

Enclosure

5 Indications for Use Statement

NOV 18 2010

510(k) Number: K102433

Device name: moorVMS-PRES Pressure Cuff Controller

Indications for use:

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Prescription Use: Yes (Part 21 CFR 801 SubpartD)	AND/OR	Over-The-Counter Use: No (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102433

1 of 1