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MAY - 4 2011

6.0 510(k) Summary

Company Name: Vasamed Incorporated.
7615 Golden Triangle Drive
Eden Prairie, MN 55344

Contact: Dan Bartnik, Chief Technology Officer & Vice President of Operations
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Summary Date: February 8, 2011

Trade Name: SensiLase® PAD-IQ

Common Name: Blood Flowmeter

Classification Name: 21 CFR 870.2100, Flowmeter, Blood; Class II.
Product Code: DPW

Predicate Device:

510(k) Number: K040654
Manufacture: Vasamed Incorporated
Trade Name: SensiLase® PAD3000

1.0 Description of Device

The SensiLase® PAD-IQ (PAD-IQ) Skin Perfusion Pressure System provides measurements of Skin Perfusion Pressure (SPP) and Pulse Volume Recording (PVR). Both measurements may be clinically applied to assess perfusion. Both the SPP and PVR measurements are features of the predicate PAD3000 device. The same methods are applied for measurement of SPP and PVR in the PAD-IQ as are applied in the predicate PAD3000.

The SPP measurement relies on the creation of reactive hyperemia. Reactive hyperemia is the transient increase in blood flow that occurs following a brief period of ischemia. The SPP measurement is performed by applying a pressure cuff capable of occluding skin blood flow

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(perfusion) to a peripheral location (arm, leg, toe, finger, etc.). The pressure cuff is inflated until the skin perfusion, as detected by a laser Doppler signal measured underneath the cuff, is determined to be near zero or significantly reduced. The pressure is released until an increase in skin perfusion is determined. The cuff pressure when the skin perfusion increases is the SPP value. SPP is a test used to evaluate peripheral microcirculation. The SPP measurement can be useful in identifying patients with peripheral arterial disease (PAD), other alterations in microcirculation, and to aid in the determination of optimum clinical treatment.

The PVR test measures and displays a waveform representing variations in the volume of blood passing through a limb during each cardiac cycle. The PVR test is fully automated and uses a partially inflated pressure cuff to apply slight pressure to the limb. The impact of blood passing through the limb is transferred to the pressure cuff where it is measured as small changes in cuff pressure. The changes are displayed as a PVR waveform. The PVR waveform can be used as a measure of functional severity of occlusive disease and as an objective baseline for later comparisons. The PVR test is sometimes referred to as air plethysmography or volume plethysmography.

The clinical application and interpretation of the SPP measurements and interpretation of the PVR Waveform is the same as the predicate PAD3000.

The differences between the predicate PAD3000 and the PAD-IQ device are summarized as:

- Change from one channel of measurement to two channels of measurement,
- Modifying device format for increased portability within a clinical environment of use,
- Inclusion of operation by battery.

2.0 Intended Use

The SensiLase® PAD-IQ provides a noninvasive measurement of Skin Perfusion Pressure (SPP) and Pulse Volume Recording (PVR) waveforms on extremities of patients.

3.0 Technology

The PAD-IQ instrument contains a laser diode that is used when performing the skin perfusion pressure measurement. Laser specifications are:

1. Laser Classification per 21CFR1040.10: Class I
2. Laser Classification per IEC 60825-1: Class 1

The same technology was applied in the predicate PAD3000 device.

Qualification of the differences between the predicate PAD3000 and the PAD-IQ device are supported by applicable FDA Recognized Consensus Standards, FDA Guidance and applicable test plans.

4.0 Conclusions

The intended use, technology, features and performance of the PAD-IQ are substantially equivalent to the predicate PAD3000. No new questions of safety or effectiveness are raised.

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

MAY - 4 2011

Vasamed Incorporated
c/o Gary Syring
Principal Consultant
Quality & Regulatory Associates, LLC
800 Levanger Lane
Stoughton,WI 53589

Re: K110438
Trade/Device Name: SensiLase® PAD-IQ
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Code: DPW
Dated: February 8, 2011
Received: February 15, 2011

Dear Mr. Syring:

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

Indications for Use

510(k) Number (if known): K110438

Device Name: SensiLase® PAD-IQ

Indications for Use:

The SensiLase® PAD-IQ provides a noninvasive measurement of Skin Perfusion Pressure (SPP) and Pulse Volume Recording (PVR) waveforms on extremities of patients.

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 K110438