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HyperMed™

JAN 15 2008

510(k) Summary

OxyVu™-1 Hyperspectral Tissue Oxygenation Measurement System (December 20, 2007)

Submittal information:

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HyperMed, Inc.
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Device name and classification

Proprietary Name:	OxyVu™-1 Hyperspectral Tissue Oxygenation Measurement System
Common Name:	Hyperspectral Tissue Oxygenation Measurement System
Classification Name:	Tissue Saturation Oximeter
Classification Panel:	Cardiovascular
CFR Section:	21 CFR 870.2700
Class:	II
Product Code:	MUD

Substantial Equivalence

The OxyVu™-1 system is substantially equivalent to the OxyVu™-1 system cleared in 510(k) K061848.

Device Description

The OxyVu™-1 system is based on hyperspectral imaging technology. The technology performs spectral analysis at each point in a two-dimensional scanned area producing an image displaying information derived from the analysis. For the OxyVu™-1 system, the spectral analysis determines in superficial tissues approximate values of oxygen saturation (HT-Sat), oxyhemoglobin levels (HT-oxy), and deoxyhemoglobin levels (HT-deoxy). The OxyVu™-1 system displays

the tissue oxygenation in a two-dimensional, color-coded image.

The system consists of:

- System console: cart, system electronics, CPU, monitor, keyboard, pointing device and printer.
- Hyperspectral imaging instrument head with support arm: broadband illuminator, camera and spectral filter for collecting hyperspectral imaging cube.
- Single use OxyVu™ Check Pads and Targets: The OxyVu™ Check Pad is used to perform an instrument check prior to patient measurements. The OxyVu™ Target is placed within the intended field of view and is used as a fiduciary mark for image registration and for focusing.

Intended Use

The OxyVu-1™ Hyperspectral Tissue Oxygenation (HTO) Measurement System is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that reports an approximate value of:

- oxygen saturation (HT-Sat),
- oxyhemoglobin level (HT-Oxy), and
- deoxyhemoglobin (HT-Deoxy) level

in superficial tissue. The OxyVu™-1 system displays two-dimensional color-coded images of tissue oxygenation of the scanned surface and reports hyperspectral tissue oxygenation measurements for selected tissue regions.

The OxyVu™-1 system is indicated for use to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise.

Comparison with the Predicate Device

	OxyVu™-1	Predicate OxyVu™-1
Measures	Oxygen saturation Oxyhemoglobin level Deoxyhemoglobin level	
Method of Measurement	Spectral analysis at specific wavelengths of light returned from target tissue.	
Output Display	Numeric Two-dimensional color map of approximate tissue oxygenation	

Similarities and Differences

External, user-observable features are essentially the same. The changes described in the Special 510(k) involve changes in the sensor illumination and in the measurement

algorithm. Changes increase robustness of operation, but not fundamental accuracy of results.

The intended uses and indications of the modified device, as described in its labeling are the same as the intended uses and indications for the unmodified predicate device.

Basis of Substantial Equivalence

The intended use and the fundamental operating specifications are unchanged. Based on virtually the same methods of validation, the OxyVu™-1 Hyperspectral Tissue Oxygenation Measurement System as modified is substantially equivalent to the OxyVu™-1 cleared in 510(k) K061848.

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Standards

Product conformity to IEC 60601-1, IEC 60601-1-1, and IEC 60601-1-2 was documented in the original 510(k), K061848. There is no new or modified statement of conformity in this Special 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

Hypermed, Inc.
c/o Mr. Chas Burr
Chas Burr Q/R Services, Inc.
11 Mystic Avenue
Winchester, MA 01890-2920

Re: K073656
OxyVu™-1 Hyperspectral Tissue Oxygenation (HTO) Measurement System
Regulation Number: 21 CFR 870.2700
Regulation Name: Tissue Saturation Oximeter
Regulatory Class: Class II (two)
Product Code: MUD
Dated: December 20, 2007
Received: December 26, 2007

Dear Mr. Burr:

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.

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" (21CFR 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 (240) 276-3150 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): K073656

Device Name: OxyVu™-1 Hyperspectral Tissue Oxygenation Measurement System

Indications for Use:

The OxyVu™-1 Hyperspectral Tissue Oxygenation (HTO) Measurement System is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that reports an approximate value of:

- oxygen saturation (HT-Sat),
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Prescription Use ___X____ (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 K073656