DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 16, 2016

Hypermed Imaging, Inc.
% Julie Powell
Vice President, Quality Assurance
Emergo Global Consulting, LLC
816 Congress Avenue, Suite 1400
Austin, Texas 78701

Re: K161237
Trade/Device Name: Hyperview Hyperspectral Tissue Oxygenation Measurement System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: November 11, 2016
Received: November 14, 2016

Dear Julie Powell:

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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

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)*
K161237

Device Name
HyperView™ Hyperspectral Tissue Oxygenation Measurement System

Indications for Use *(Describe)*
The HyperView™ Hyperspectral Tissue Oxygenation Measurement System is intended for use by physicians/healthcare professionals as a noninvasive tissue oxygenation measurement system that reports an approximate value of:

- oxygen saturation (O2Sat),
- oxyhemoglobin level (Oxy), and
- deoxyhemoglobin (Deoxy) level

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

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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Section 5 – 510(k) Summary

Hyperview Hyperspectral Tissue Oxygenation Measurement System

K161237

1. Submission Sponsor

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USA

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2. Submission Correspondent

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3. Date Prepared

April 29, 2016

4. Device Identification

Trade/Proprietary Name:	HyperView™ Hyperspectral Tissue Oxygenation Measurement System
Common/Usual Name:	Tissue Saturation Oximeter
Classification Name:	Oximeter
Regulation Number:	21 CFR 870.2700
Product Code:	MUD, Oximeter
Device Class:	Class II
Classification Panel:	Cardiovascular

5. Legally Marketed Predicate Device(s)

OxyVu™-1, 510(k) K073656, HyperMed, Inc.

6. Device Description

HyperMed Imaging Inc.'s HyperView handheld hyperspectral imaging system consists of the HyperView Camera and the HyperView Accessories Kit that includes a Docking Station, Calibration Verification System, Power Cord and USB Cable Set.

The HyperView system provides noninvasive measurement of approximate tissue oxygenation, sensitive to local, regional, and systemic low/no-flow ischemia. HyperView uses multi-wavelength imaging technology to analyze the signature of light as it is absorbed by the patient's tissue. The HyperView system analyzes these light absorption signatures to measure oxyhemoglobin and deoxyhemoglobin levels in the tissue, and creates a color-coded image that illustrates relative concentrations of oxygenated hemoglobin and deoxygenated hemoglobin.

Quantitative data is provided for oxyhemoglobin and deoxyhemoglobin levels as well as oxygen saturation. The technology is suitable for surface assessment, as the visible spectrum light used penetrates no more than a few millimeters deep.

The HyperView is a handheld product consisting of several subassemblies including precision optical components, electro-optics, imaging sensors, a thermal sensor, flash illumination, flex circuits, printed circuit boards, a battery, plastics as well as image processing and graphics user interface software. Users will interact with the device using a built-in, resistive, touchscreen display and an image capture button similar to a digital camera. The product does not come in contact with the patient and no injectable contrast is required. The camera uses visible light to momentarily illuminate the patient's skin for photographic imaging. Such information is useful in determining viability of vascular delivery in the superficial skin and correspondingly, such information can assist the physician in determining the ability of the patient's vascular system to support normal tissue health and wound healing.

7. Indication for Use Statement

The HyperView™ Hyperspectral Tissue Oxygenation Measurement System is intended for use by physicians/healthcare professionals as a noninvasive tissue oxygenation measurement system that reports an approximate value of:

- oxygen saturation (O2Sat),
- oxyhemoglobin level (Oxy), and
- deoxyhemoglobin (Deoxy) level

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

8. Substantial Equivalence Discussion

The following table compares the HyperView system to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table 5-A – Comparison of Characteristics

	SUBJECT DEVICE	**PREDICATE**	**Significant Differences**
Manufacturer	**HyperMed Imaging, Inc.**	**HyperMed, Inc.**	
Trade Name	**HyperView™ System**	**OxyVu™-1**	
Product Code	MUD	MUD	Same
Regulation Number	21 CFR 870.2700	21 CFR 870.2700	Same
Regulation Name	Tissue Saturation Oximeter	Tissue Saturation Oximeter	Same
Indications for Use	The HyperView™ Hyperspectral Tissue Oxygenation Measurement System is intended for use by physicians/healthcare professionals as a noninvasive tissue oxygenation measurement system that reports an approximate value of: • oxygen saturation (O2Sat), • oxyhemoglobin level (Oxy), and	The OxyVu™-1 Hyperspectral Tissue Oxygenation (HTO) Measurement System is intended for use by healthcare professionals as a noninvasive tissue oxygenation measurement system that reports an approximate value of: • oxygen saturation (HT-Sat), • oxyhemoglobin level (HT - Oxy), and	Same

	SUBJECT DEVICE	PREDICATE	Significant Differences
Manufacturer	**HyperMed Imaging, Inc.**	**HyperMed, Inc.**	
Trade Name	**HyperView™ System**	**OxyVu™-1**	
	• deoxyhemoglobin (Deoxy) level in superficial tissue. The HyperView™ 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 HyperView™ system is indicated for use to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise.	• 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.	
System Components	• Hand-held, battery operated device including built in resistive touchscreen control and user interface software • PC software application for reports • Desktop docking station to provide battery charging and USB to computer data interface • USB computer interface • Optionally tripod mountable • Calibration verification cards are only required to be used by user for periodic verification of calibration • Laser verification cards are used for periodic verification of laser alignment	• System Console: Cart, System Electronics, CPU, Monitor, Keyboard, Pointing Device and Printer (AC powered) • Hyperspectral imaging instrument head with support arm: broadband illuminator, camera and spectral filter for collecting hyperspectral imaging cube • Single use OxyVu™ Check Pads for calibration	Different; the update of the system from the cart-based unit to a hand-held device involved changes to the product dimensions, user interface, power source, and packaging. The change from cart-based unit to hand-held unit had no effect on performance. There were no additional safety or effectiveness concerns as the hyperspectral technology used is the same.
Calibration	Unit is factory calibrated	Calibration is required	Similar; both require

	SUBJECT DEVICE	PREDICATE	Significant Differences
Manufacturer	**HyperMed Imaging, Inc.**	**HyperMed, Inc.**	
Trade Name	**HyperView™ System**	**OxyVu™-1**	
	and does not require calibration before each use.	before each use	calibration. The change in calibration frequency had no effect on performance. The change in calibration frequency does not present any additional safety or effectiveness concerns.
Time per patient image	< 1 second capture time 5 – 10 minutes use	3 minute capture time 10 to 15 minutes use	Similar method to capture images. Multiple images are captured simultaneously to reduce imaging time. The change in image time had no effect on performance. The patient image time change does not present any additional safety or effectiveness concerns.
Spectrum of Light Used	Visible Spectrum Light (400nm to 700nm)	Visible Spectrum Light (400nm to 700nm)	Same
Wavelengths of Light Used for Data Analysis and Imaging	8 Wavelengths	15 Wavelengths	Similar; subject device uses a subset of 8 of the 15 wavelengths used by the predicate. The change in number of wavelengths had no effect on performance. The change in number of wavelengths does not present any additional safety or effectiveness concerns.
LEDs	CREE LEDs (filtered)	CREE LEDs (3.0 mW/cm^2)	Similar; both use LEDs.

	SUBJECT DEVICE	PREDICATE	Significant Differences
Manufacturer	**HyperMed Imaging, Inc.**	**HyperMed, Inc.**	
Trade Name	**HyperView™ System**	**OxyVu™-1**	
	Illuminator 1: 11.0 mW/cm^2 Illuminator 2: 6.1 mW/cm^2	(unfiltered)	The change in LEDs and the filtering of their output had no effect on performance. The LED change does not present any additional safety or effectiveness concerns.
LED/Laser Classification	Class II Laser	Class I LED	Different; LED/Laser classification changed from Class I to Class II. The classification difference had no effect on performance and does not present any additional safety or effectiveness concerns.
Software	C, C^{++}, Java and .net (for PC application)	Matlab and Java	Similar as both use software. The change in programming languages had no effect on performance. This change does not present any additional safety or effectiveness concerns.
Region of Interest (ROI) Area	Support for freehand drawing ROI selection (mm^2)	Support for freehand drawing ROI selection (mm^2)	Same
Image Type	Diagnostic	Diagnostic	Same
Measures	Oxygen saturation Oxyhemoglobin level Deoxyhemoglobin level	Oxygen saturation Oxyhemoglobin level Deoxyhemoglobin level	Same
Method of Measurement	Spectral analysis at specific wavelengths of light returned from target (8 wavelengths, which are a subset of the original 15	Spectral analysis at specific wavelengths of light returned from target (15 wavelengths)	Similar; as both use wavelengths of light for measurement. The wavelengths for the

	SUBJECT DEVICE	PREDICATE	Significant Differences
Manufacturer	**HyperMed Imaging, Inc.**	**HyperMed, Inc.**	
Trade Name	**HyperView™ System**	**OxyVu™-1**	
	wavelengths)		hand-held subject device are a subset of the wavelengths used in the predicate device and the change from 15 to 8 wavelengths had no effect on performance. This change does not present any additional safety or effectiveness concerns.
Output Display	Numeric Two-dimensional color map of approximate tissue oxygenation	Numeric Two-dimensional color map of approximate tissue oxygenation	Same
Graphical Images	• VIS – Visible • Sat – Saturation Map (new map based upon the oxygen saturation level) • Oxy – Tissue oxygenation map • Deoxy – Tissue deoxyhemoglobin map • Note: The HSI map replaced with Saturation Map.	• VIS – Visible • HSI – Tissue oxygenation map of oxyhemoglobin and deoxyhemoglobin • Oxy – Tissue oxygenation map • Deoxy – Tissue deoxyhemoglobin map Note: The Oxygen Saturation value displayed without a map.	Similar; both use same graphical images for VIS, Oxy, Deoxy. The HSI map was replaced with the Saturation Map. The change from an HSI to an oxygen saturation map had no effect on performance. This change does not present any additional safety or effectiveness concerns.
Selection Tools	Circle Region Perimeter with optional second region	Circle Region Perimeter	Similar; both devices use the same Selection Tools, with added feature for the Perimeter Tool. The additional feature in the Perimeter Selection Tool had no effect on how the device performed. This change does not present any additional safety or

	SUBJECT DEVICE	PREDICATE	Significant Differences
Manufacturer	**HyperMed Imaging, Inc.**	**HyperMed, Inc.**	
Trade Name	**HyperView™ System**	**OxyVu™-1**	
			effectiveness concerns.
Data Storage	DICOM images stored on device	Images stored in Matlab files	Similar; as both have data storage capabilities. The change in data storage type (to an industry standard format) had no effect on performance of the device. This change does not present any additional safety or effectiveness concerns.
Operating Distance from Patient	Approximately 15”	Approximately 17”	Similar; both products have approximately the same working distance from the patient. The change in operating distance from the patient had no effect on device performance. This change does not present any additional safety or effectiveness concerns.
Imaged Area	100 mm x 100 mm	80 mm x 80 mm	Similar; imaged area is increased with hand-held subject device. The increase in image area had no effect on performance. This change does not present any additional safety or effectiveness concerns.
Electrical Safety Testing Passed	Yes ANSI/AAMI ES60601-1:2005/(R)2012 IEC 60601-1-2:2007	Yes IEC 60601-1 IEC 60601-1-2	Same

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of the HyperView system, and in showing substantial equivalence to the predicate device of this 510(k) submission, HyperMed completed a number of tests. The HyperView system meets all requirements for design characteristics, non-clinical performance testing, EMC/EMI testing, electrical safety, laser safety and battery safety testing to confirm that the output meets the design inputs and specifications for the device.

The HyperView system passed all testing in accordance with internal requirements, national standards, and international standards shown below to support substantial equivalence of the subject device:

- Software verification and validation testing per FDA Guidance and IEC 62304: conformance of software development life cycle for the HyperView System and compliance to the requirements of the FDA guidance document for software contained in a medical device.
- Electrical safety testing per ANSI/AAMI ES60601-1: **PASS**
- Electromagnetic compatibility testing per IEC 60601-1-2: **PASS**
- Laser safety testing per IEC 60825-1:2007: **PASS**
- Photobiological safety of lamps and lamp systems per IEC 62471:2006: **PASS**
- Secondary cells and batteries safety testing per IEC 62133:2012 : **PASS**
- Transportation safety testing of Lithium Batteries per UN 38.3:2009: **PASS**
- Transit testing per ASTM D4169:2014: **PASS**

The HyperView passed all the testing in accordance with internal requirements, national standards, and international standards shown above to support substantial equivalence of the subject device.

10. Clinical Performance Data

A validation study was performed with the HyperView system for assessing the hyperspectral imaging in persons with vascular disease and / or diabetes mellitus and potentially compromised tissue oxygenation. The study was conducted to evaluate the HyperView handheld system with the predicate OxyVu^{TM}-1 console system device. The study was performed in compliance with Good Clinical Practices (GCP) with subjects enrolled in an IRB approved study that were consented for participation according to the intended use of the device, defined inclusion criteria, and defined exclusion criteria; with the purpose of meeting the study objectives.

The study objectives were defined as the following:

- Comparison of hyperspectral imaging tissue oxygenation as the difference in the mean tissue oxygen saturation (O2Sat) measurements of the OxyVu™-1 compared to the HyperView handheld system.

- Secondary endpoints for this study include testing of mean oxyhemoglobin (Oxy) and deoxyhemoglobin (Deoxy) levels with stratification by the following:
  - Skin pigmentation and melanin concentration levels
  - Non-ulcerated and ulcerated areas
  - Degree of peripheral artery disease in the study limb

The clinical study was planned for a minimum of 20 (twenty) subjects to be enrolled, which was met. The subjects had images taken of target areas with both the HyperView handheld system and the predicate device, during a single session. No follow up visits were required.

The outcomes measurements for the clinical study are summarized as follows:

Primary Efficacy Endpoint Results

The pre-specified primary efficacy endpoint for the validation study was to compare the O2Sat measurement difference between the investigational HyperView and predicate OxyVu™-1 device ((HyperView O2Sat minus OxyVu™-1 O2Sat).

A Student's t-tests was performed using SAS version 9.4 (SAS Institute Inc., Cary, NC) to compare the mean differences with non-adjusted results. A difference that is not greater than 7% nor less than -7% between the mean O2Sat values for each device was deemed substantially equivalent.

A mean O2Sat difference of 3.22 +/- 3.38% was demonstrated between the HyperView and the OxyVu™-1 devices in this study. Lower confidence intervals and upper confidence intervals were 2.58% and 3.87% respectively.

A second analysis was performed comparing the study limbs by image sequence. The conclusions remained the same. The mean differences in O2Sat between the devices were 3.17%, 3.0% and 3.5% respectively.

Secondary Efficacy Endpoint Results

Secondary objectives entailed assessing O2Sat, Oxy, and Deoxy differences stratified by skin tone, presence of ulcers, and an ABI indicative of peripheral artery disease.

Stratification by Skin Tone:

The mean difference was 2.42% for the light skin tone and 4.64% for medium skin tone. While the means of these two groups were statistically different (P>.0002), the mean values and confidence intervals were all within a 5% difference between the two cameras.

An analysis on the index forearm region was also performed, as all three skin tone groups were represented for this location (light, medium, and dark). In this location, there were no

statistically significant differences noted between the skin tone groups (P>0.1968). The mean differences were 4% or less for all three groups.

Stratification by Non-ulcerated and Ulcerate Study Limbs

Eleven study limbs (31%) had a foot ulcer present. Each study limb had 3 sets of paired images for a total of 33 paired data sets. The mean difference in O2Sat between the devices was 1.91% with lower and upper confidence intervals of 0.55% and 3.26% in study limbs with a foot ulcer and 3.8% when ulcers were not present. The mean O2Sat difference was significantly smaller between the devices when ulcers were present on the foot (P>0.0068).

Stratification by Peripheral Artery Disease (PAD) of the Study Limb

There were 15 study limbs that met this definition. The mean difference in O2Sat for this group was 2.6% with lower and upper confidence intervals of 1.14% and 4.06% respectively.

There were no statistically significant differences noted between the device measurements of O2Sat between study limbs with PAD compared to study limbs without PAD (P>0.4449).

Oxy Differences

An assessment was made of the difference in Oxy for paired images. Oxy values are on a numeric scale of 0 to 255. A mean Oxy difference of 14.07 (5.5%) was observed between the two devices.

Oxy differences by skin tone on the plantar surface of the foot demonstrated mean difference of 11.94 (4.7%) in light skin toned feet and 17.85 (7.0%) in medium skin toned feet.

Oxy differences by skin tone on the forearm demonstrated a mean difference of 12.62 (4.9%) in light toned skin, 13.64 (5.3%) in medium toned skin, and 17.5 (6.8%) in dark toned skin.

Differences in Oxy between the two devices with an ulcer present was 11.3 (4.4%).

Difference in Oxy between for subjects with peripheral artery disease was 12.27 (4.8%).

Deoxy Differences

An assessment was made of the difference in Deoxy for paired images. Deoxy values are on a numeric scale of 0 to 255. A mean difference of 1.95 (0.8%) was observed.

Deoxy differences by skin tone on the plantar surface of the foot demonstrated mean difference of 2.9 (1.1%) in light skin toned feet and 0.28 (0.1%) in medium skin toned feet.

Deoxy differences by skin tone of the forearm demonstrated a mean difference of 2.47 (1.0%) in light toned skin, 1.1 (0.4%) in medium toned skin, and 2.38 (0.9%) in dark toned skin.

Deoxy values between the two devices for study limbs with ulcerated tissue (challenged tissue) demonstrated a mean difference of 3.09 (1.2%).

The difference in Deoxy between the two devices in study limbs with PAD was 3.27 (1.3%).

The validation study concluded that the HyperView system is safe and effective for its intended use and the outcomes of the study met the stated objectives. The validation study supports the indication for use as a noninvasive tissue oxygenation measurement system that reports approximate values of

oxygen saturation (O2Sat), oxyhemoglobin level (Oxy), and deoxyhemoglobin (Deoxy) level in superficial tissue.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device or the device has the same intended use and different technological characteristics provided it can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device.

The HyperView™ Hyperspectral Tissue Oxygenation Measurement System, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device.