DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 21, 2016

Modulated Imaging, Inc.
% Maureen O'Connell
President
O'Connell Regulatory Consultants, Inc.
5 Timber Lane
North Reading, Massachusetts 01864

Re: K153426
Trade/Device Name: Ox-Imager CS
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: November 29, 2016
Received: November 30, 2016

Dear Maureen O'Connell:

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.

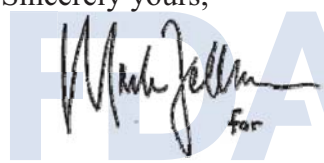
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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)*
K153426

Device Name
Ox-Imager CS

Indications for Use *(Describe)*
The Ox-Imager CS™ 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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This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

General Information

510(k) Owner:	Modulated Imaging, Inc. 17151 Gillette Ave Irvine, CA 92614 David Cuccia Telephone: 949-596-7492
Contact Person:	Maureen O'Connell Regulatory Consultant Telephone: 978-207-1245 Email: Maureen@oconnellregulatory.com
Summary Preparation Date:	December 16, 2016

Device Information

Device Trade Names:	Ox-Imager CS
Common Name:	Oximeter
Classification Name:	Oximeter, Tissue Saturation (21 CFR 870.2700, Product Code: MUD)

Predicate Device

Device Name:	Hypermed, Inc. OxyVu-1 System
510(k) Clearance Number:	K073656

Device Description

The Ox-Imager CS™ is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that maps value of: oxygen saturation, oxy-hemoglobin, and deoxy-hemoglobin into 2D/3D visual presentations. The Ox-Imager™ CS is a non-contact imaging device to visualize spatially-resolved optical and functional parameters of biological tissue. The Ox-Imager CS shares fundamental principles with other oximeters and tissue oxygenation measurement systems. Spectral analysis is used to measure oxygen saturation (StO_2), oxyhemoglobin (HbO_2), deoxyhemoglobin (HbR) and determine tissue optical properties (absorption and scattering) using specific LED wavelengths and patterns. The Ox-Imager CS uses both visible (VIS) and near-

infrared (NIR) wavelengths; other systems that also measure oxygenation levels in superficial tissue may use only VIS or NIR wavelengths. Tissue oximetry exposes tissue to optical radiation of known wavelengths and captures the remitted light or reflectance. The remitted back scattered light is then used to calculate the tissue constituents mentioned above based on principles of multi-spectral imaging and Spatial Frequency Domain Imaging (SFDI).

Intended Use
The Ox-Imager CS™ system is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that reports an approximate value of:

- Oxygen Saturation (StO_2)
- Oxy-hemoglobin (HbO_2), and
- Deoxy-hemoglobin (HbR)

in superficial tissue.

Indications for Use
The Ox-Imager CS™ is indicated for use to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise.

Technological Characteristics and Substantial Equivalence
The following table provides a comparison of the intended use and technological characteristics of the Ox-Imager CS to the predicate device, OxyVu-1 System. In addition to the OxyVu-1 System, the Kent Camera was used as a reference device.

Manufacturer	**Modulated Imaging**	**Hypermed, Inc.**	**Differences and Similarities between Subject and Predicate Device**
Product Name	**Ox-Imager CS**	**OxyVu-1 system**	
510(k) Number	K153426	K073656	
Product Code	MUD	MUD	
Indications for Use	The Ox-Imager CS is indicated for use to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise.	The OxyVu-1 system is indicated for use to determine oxygenation levels in superficial tissues in patients with potential circulatory compromise.	Same
Clearance Type	Prescription	Prescription	Same
Measurement Method	Structured illumination and spectral model-based analysis of light returned from target tissue.	Spectral model-based analysis of light returned from target tissue.	Similar Spatial Frequency Domain Imaging (SFDI) is used as an adjunct method to fit spectra.
Data Display	Numeric and two dimensional color map of tissue oxygenation.	Numeric and two dimensional color map of tissue oxygenation.	Same

Measurements Made	Oxygen Saturation Oxy-hemoglobin level Deoxy-hemoglobin level	Oxygen Saturation Oxy-hemoglobin level Deoxy-hemoglobin level	Same
Wavelength of Detection	Imager uses discrete illumination wavelengths and camera for collecting hyperspectral images between 450 and 1000nm	Imager uses a broadband illuminator, camera and a spectral filter for collecting hyperspectral images using 15 wavelengths between 500 and 660nm.	Similar Wavelength range for Ox-Imager CS includes both visible and near-infrared light (see reference)
Measurement Sensor	CCD Camera	CCD Camera	Same
Measurement Time	<30s	< 30s	Same
Data Output	Display of color map data and print-ready PDF of report	Display of color map data and print of report	Same
Data Storage	CPU Hard disk	CPU Hard disk	Same
Analysis Method	Uses oxy-hemoglobin and deoxy-hemoglobin spectra and structured illumination to fit the measured tissue spectra and determine tissue optical properties (absorption and scattering). Oxygen saturation is calculated from the oxy-hemoglobin and deoxy-hemoglobin fit coefficients.	Uses oxy-hemoglobin and deoxy-hemoglobin spectra and a slope and offset to fit the measured tissue spectra. Oxygen saturation is calculated from the oxy-hemoglobin and deoxy-hemoglobin fit coefficients.	Similar Spatial Frequency Domain Imaging (SFDI) is used as an adjunct method to fit spectra.
Location of Measurement	Two-dimensional area of superficial microvasculature	Two-dimensional area of superficial microvasculature	Same
Patient Contact	None	Uses a disposable Target Pad placed on patient near the area of interest	Same as reference device

Reference Table

Manufacturer	**Modulated Imaging**	**Kent Imaging, Inc.**	**Differences and Similarities between Subject and Reference Device**
Product Name	**Ox-Imager CS**	**Kent Camera**	
510(k) Number	K153426	K113507	
Product Code	MUD	MUD	
Indications for Use	The Ox-Imager CS is indicated for use to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise.	The Kent Camera is indicated for use to determine oxygenation levels in superficial tissues in patients with potential circulatory compromise.	Same
Clearance Type	Prescription	Prescription	Same
Measurement Method	Structured illumination and spectral model-based analysis of light returned from target tissue.	Spectral model-based analysis of light returned from target tissue.	Similar Spatial Frequency Domain Imaging (SFDI) is used as an adjunct method to fit spectra.
Data Display	Numeric and two dimensional color map of tissue oxygenation.	Numeric and two dimensional color map of tissue oxygenation.	Same
Measurements Made	Oxygen Saturation Oxy-hemoglobin level Deoxy-hemoglobin level	Oxygen Saturation Oxy-hemoglobin level Deoxy-hemoglobin level	Same

Wavelength of Detection	Imager uses discrete illumination wavelengths and camera for collecting hyperspectral images between 450 and 1000nm	Imager collects multiple hyperspectral images in the near-infrared (600-1000nm)	Similar Wavelength range for Ox-Imager CS includes both visible and near-infrared light (see predicate)
Patient Contact	None	None	Same

Modulated Imaging's Ox-Imager CS is substantially equivalent to the Hypermed, Inc. OxyVu-1 Hyperspectral Tissue Oxygenation (HTO) Measurement System cleared in K073656. The Ox-Imager CS and the OxyVu-1 system have identical Indications for Use and identical Intended Use. Both devices use similar core technology and display data in a similar context. Performance testing shows equivalent results between the two systems.

Although there are many similarities between the Ox-Imager CS and the OxyVu-1 System, there are also minor differences in the technological characteristics. Both of the systems are non-invasive tissue oxygenation measurement systems that report an approximate value of: oxygen saturation (StO_2), oxy-hemoglobin level (HbO_2), and deoxy-hemoglobin (HbR) level in superficial tissue. Both of the systems display two-dimensional color-coded images of tissue oxygenation of the scanned surface and report approximate tissue oxygenation measurements for selected tissue regions. The data display and the measurements made are all the same.

Regarding the wavelength of detection, the Ox-Imager CS uses discrete visible and near-infrared wavelengths between 450 and 1000 nm and a CCD camera for collecting hyperspectral images while the OxyVu-1 System uses a broadband illuminator camera and a spectral filter for collecting hyperspectral images using 15 wavelengths between 500 and 660 nm. The reference device Kent Camera (K113507) is similar to the Ox-Imager CS device as it uses near-infrared wavelengths for detection. Performance data is provided which compares the Ox-Imager CS to the OxyVu-1 and demonstrates substantial equivalence.

Performance Data

The OxyVu-1 was tested and found to conform with the following recognized consensus standards:

- AAMI ANSI ES 60601-1:2005 +A1:2012 Medical electrical equipment-Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests
- IEC 60825-1 Edition 2.0 Safety of Laser Products-Part 1: Equipment Classification and Requirements
- IEC 62366 Edition 1.0: Medical Devices-Part 1: Application of Usability Engineering to Medical Devices

Benchtop, pre-clinical and clinical performance data was provided which established that the Ox-Imager CS is substantially equivalent to the predicate OxyVu-1 device.

A clinical study was conducted which compared the Ox-Imager CS to the predicate device. The objective of the study was to establish that the Ox-Imager CS is substantially equivalent to the predicate HyperMed OxyVu-1 device. Circulatory compromise was mimicked by performing a vascular occlusion test using both devices and determine whether there is a statistically significant decrease in tissue oxygen saturation (StO_2) between baseline and compromised tissue states. It was demonstrated that the predicate OxyVu-1 and the Ox-Imager CS recover highly correlated values of StO_2 during the time course of a vascular occlusion test and that both devices measured a statistically significant decrease in tissue oxygen saturation (StO_2) after circulatory compromise.

Additional testing included a blood phantom desaturation study, conducted to correlate changes in tissue oxygen saturation (StO_2) to pO_2. The pO_2/StO_2 curves showed strong agreement with expected StO_2 values. Also, a pre-clinical study was conducted in rabbits that correlated co-oximeter values (SaO_2/SvO_2) from blood draws to tissue oxygen saturation (StO_2) during an inspired oxygen challenge. Results showed a strong linear and monotonic relationship between blood gas values and Ox-Imager CS measurements as fraction of inspired oxygen (FiO_2) was changed. Finally, a clinical study was conducted which compared tissue oxygen saturation values (StO_2) to transcutaneous oxygen measurements ($tcpO_2$) during a vasculature occlusion test meant to mimic transient ischemia. Average values at baseline and at the end of occlusion (tissue compromise state) were compared to determine sensitivity to circulatory compromise. The shape of both curves during transient ischemia matched literature and there was a significant change in both StO_2 and $tcPO_2$ values between baseline and tissue compromise timepoints.

Additionally, the Kent Camera is provided as a reference device because of its shared use of near-infrared wavelengths which support the technical approach used in the Ox-Imager CS's method of measurement.

Risk/Benefit Information
The Ox-Imager CS does not provide any medical diagnosis in and of itself and is intended to be part of a larger assessment battery, as described in the instructions for use. The risk to patients is minimal since the Ox-Imager CS is a non-contact, non-invasive device.

The Ox-Imager CS is intended for use in conjunction with other clinical assessment and diagnostic tests. It is not intended to diagnose disease or prescribe a medical course of treatment.

Biocompatibility
There are no patient contacting components in the Ox-Imager CS.