July 19, 2018

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

Re: K181623
Trade/Device Name: Clarifi Imaging System
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: June 19, 2018
Received: June 20, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181623

Device Name
Clarifi™ Imaging System

Indications for Use *(Describe)*
The Clarifi™ Imaging 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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: 949-825-5070
Contact Person:	Maureen O'Connell Regulatory Consultant Telephone: 978-207-1245 Email: Maureen@oconnellregulatory.com
Summary Preparation Date:	July 16, 2018

Device Information

Device Trade Names:	Clarifi™ Imaging System
Common Name:	Oximeter
Classification Name:	Oximeter, Tissue Saturation (21 CFR 870.2700, Product Code: MUD)
Submission Type:	Special 510(k)
Submission Reason:	Device Modifications

Predicate Device

Device Name:	Ox-Imager CS System
510(k) Clearance Number:	K153426

Intended Use

The Clarifi Imaging 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)
- Oxyhemoglobin (HbO_2), and
- Deoxyhemoglobin (HbR)

in superficial tissue.

Indications for Use
The Clarifi™ Imaging System is indicated for use to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise.

Device Description
The Clarifi Imaging System is a noninvasive non-contact imaging device used to visualize spatially-resolved functional parameters of biological tissue. The Clarifi Imaging System shares fundamental principles with other oximeters and tissue oxygenation measurement systems. 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. Spectral analysis is used to measure tissue oxygen saturation (StO_2), oxyhemoglobin (HbO_2), deoxyhemoglobin (HbR), and total hemoglobin (HbT: superficial and subsurface hemoglobin) and determine tissue optical properties (absorption and scattering). The Clarifi Imaging System 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. The analysis for Clarifi is based on principles of multi-spectral imaging and Spatial Frequency Domain Imaging (SFDI).

Device Modifications
The device modifications were made primarily to address parts obsolescence and manufacturability. The changes included revising the projector and camera design, changing the LED vendor, increasing the field of view, updating the PC board and firmware design, replacing the battery and the aiming laser.

Technological Characteristics and Substantial Equivalence
Modulated Imaging's Clarifi Imaging System is substantially equivalent to the company's Ox-Imager CS ("the predicate device", K153426). As explained in more detail below, Clarifi has the same intended use and indications for use, and principles of operation as the previously cleared predicate device, with one minor difference in a technological characteristic. A substantial equivalence chart comparing the similarities and differences between the Clarifi and its predicate device is provided below.

The Clarifi System is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement to determine oxygenation levels in superficial tissues for patients with potential circulatory compromise. The system reports an approximate value of oxygen saturation, oxyhemoglobin levels, deoxyhemoglobin levels and total hemoglobin levels in superficial tissue.

The Clarifi 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 Clarifi and the Ox-Imager CS system have identical Indications for Use and identical Intended Use. Both devices use the same core technology and display data in the same context.

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

Manufacturer	**Modulated Imaging, Inc.**	**Modulated Imaging, Inc.**	**Differences and Similarities between Subject and Predicate Device**
Product Name	**Ox-Imager CS (Predicate)**	**Clarifi™ Imaging System (Subject)**	-
510(k) Number	K153426	-	-
Product Code	MUD	MUD	Same
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 Clarifi™ Imaging System is indicated for use to determine oxygenation levels in superficial tissues for 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.	Structured illumination and spectral model-based analysis of light returned from target tissue.	Same
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, Oxyhemoglobin level, Deoxyhemoglobin level, Total hemoglobin level	Oxygen Saturation, Oxyhemoglobin level, Deoxyhemoglobin level, Total hemoglobin level	Same
Wavelength of Detection	Imager uses discrete illumination wavelengths and camera for collecting hyperspectral images between 450nm and 1000nm	Clarifi uses discrete illumination wavelengths and cameras for collecting hyperspectral images between 450nm and 1000nm	Same
Measurement Sensor	CCD	CMOS	Substantially Equivalent (see SE discussion)
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- ready PDF 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 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.	Same
Location of Measurement	Two-dimensional area of superficial microvasculature	Two-dimensional area of superficial microvasculature	Same
Patient Contact	None	None	Same
Form factor	Cart-based system ~9.5" x 8.5" x 7.5" Head Unit	Cart-Based System; ~8" x 3.5" x 7.5" Head Unit	Similar (see SE discussion)

Performance Data

The Clarifi Imaging System 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 Edition 4.0 Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests
- IEC 60601-2-57 Edition 1.0 Particular Requirements for the Basic Safety and Essential Performance of Non-Laser Light Source Equipment Intended for Therapeutic, Diagnostic, Monitoring and Cosmetic/Aesthetic Use
- 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
- IEC 60601-2-57 Edition 1.0 Medical Electrical Equipment Part 2-57: Particular Requirements for the Basic Safety and Essential Performance of Non-Laser Light Source Electrical Equipment Intended for Therapeutic, Diagnostic, Monitoring and Cosmetic/Aesthetic Use

Performance Testing

Bench performance data were conducted under design validation 21 CFR 820.30(g). In a first set of tests, bench performance verification testing was performed to confirm the linearity, precision, and stability of the Clarifi Imaging System reflectivity (R_d) measurements. Using NIST-traceable Spectralon standards, a strong, linear agreement ($r^2>0.9$) of diffuse reflectivity is found between the predicate device (Ox-Imager CS - K153426) and the subject device. The precision of the Clarifi Imaging System is shown to be within specifications (<5% error), and measurement stability is acceptable (<1% drift). Additional testing on reflectance targets verified the device imaging performance. Image homogeneity (< 4 % roll-off), and signal-to-noise ratio (SNR>40) are of sufficient quality.

In summation, these data confirm that the Clarifi Imaging System is substantially equivalent to the Ox-Imager CS.