



MIMOSA Diagnostics Inc
Yuan Fang
Chief Regulatory Officer
1 Yonge St., Suite 201
Toronto, CA M5E1E5 Ontario

November 1, 2019

Re: K190334

Trade/Device Name: MIMOSA Imager
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: Class II
Product Code: MUD
Dated: October 1, 2019
Received: October 4, 2019

Dear Yuan Fang:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see <https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products>); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance>) and CDRH Learn (<https://www.fda.gov/training-and-continuing-education/cdrh-learn>). 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 (<https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R.P. Ogden, MS
Assistant Director, THT4A4
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K190334

Device Name

MIMOSA Imager

Indications for Use (Describe)

The MIMOSA Imager is intended to non-invasively estimate the spatial distribution of percent oxygen saturation (StO₂) in a volume of tissue. This is performed in medical environments including physician offices, hospitals, ambulatory care and Emergency Medical Services.

The MIMOSA Imager is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."



510(k) Summary

[As required by 21 CFR 807.92]

Submitter's Name: MIMOSA Diagnostics, Inc.
Address: 1 Yonge Street, Suite 201, Toronto, ON M5E 1E5
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Date Summary was prepared: October 29, 2019

Information Regarding the device classification:

Trade Name: MIMOSA Imager
Common Name: Tissue Oximeter
Classification Regulation: 21 CFR 870.2700
Classification Regulation Name: Oximeter
Product Code: MUD
Device Class: II

Information regarding the legally marketed device to which we are claiming equivalence [807.92(a)(3)]:

510(k) Reference #: K042657
Device Name: ODISsey Tissue Oximeter
510(k) Holder: ViOptix, Inc.

Information regarding Reference Devices with the MUD product code:

Reference Device:

510(k) Reference #: K113507
Device Name: Kent Camera
510(k) Holder: Kent Imaging, Inc.



Description of the Device:

The MIMOSA Imager is a non-contacting, cordless, battery powered device that non-invasively estimates the percent oxygen saturation (StO₂) in a volume of tissue. The device captures spatially-resolved images that is triggered by the end user via a smartphone-app interface. By tracking the spectral signatures of dominant chromophores in the patient’s superficial tissue, the device calculates and displays the StO₂ estimate on the connected android device screen.

The MIMOSA Imager is intended for use by healthcare professionals as a non-invasive tissue oxygenation measurement system that maps the tissue oxygen saturation (StO₂) values to a spatially registered heat-map. The MIMOSA Imager 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 or reflected light. The remitted back scattered light is then used to calculate StO₂ based on principles of multispectral imaging. Spectral analysis is used to measure StO₂ using specific both visible (VIS) and near-infrared (NIR) LED-illuminated wavelengths. Other systems that also measure oxygenation levels in superficial tissue may use only VIS or NIR wavelengths.

Indications for Use:

The MIMOSA Imager is intended to non-invasively estimate the spatial distribution of percent oxygen saturation (StO₂) in a volume of tissue. This is performed in medical environments including physician offices, hospitals, ambulatory care and Emergency Medical Services.

The MIMOSA Imager is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.

Substantial Equivalence Comparison

Parameter	Subject Device: MIMOSA IMAGER	Predicate Device (ODISsey)	Comparison
510k #	This Submission	K042657	
Indications for Use	The MIMOSA Imager is intended to non-invasively estimate the <u>spatial distribution of</u> percent oxygen saturation in a volume of tissue (StO ₂). This is performed in medical environments including physician offices, hospitals, ambulatory care and Emergency Medical Services.	The ViOptix ODISsey Tissue Oximeter is intended to non-invasively estimate the percent oxygen saturation in a volume of tissue (StO ₂). This is performed in medical environments including physician offices, hospitals, ambulatory care and Emergency Medical Services.	Similar: only difference is “spatial distribution of.”



	The MIMOSA Imager is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.	The ODISsey Tissue Oximeter is indicated for use in monitoring patients during circulatory or perfusion examinations of skeletal muscle or when there is a suspicion of compromised circulation.	
Measured Parameters	Tissue oxygen saturation (StO ₂) information	Tissue oxygen saturation (StO ₂) information	Same
Operating Principle	Spectrophotometric oximetry	Spectrophotometric oximetry	Same
Light Source	Near-infrared light Source: LED chips Wavelengths: 620, 630, 700, 810, 880, 980 nm	Near-infrared light Source: laser diodes Wavelengths: 690, 830 nm	Similar: the MIMOSA Imager delivers additional wavelengths of light to the tissue in order to improve measurement reliability and providing a more robust dataset. The additional wavelengths have been assessed based on IEC 62471 and were found to not pose any safety concerns and effectiveness demonstrated through performance (bench and clinical) testing . This does not raise any new questions in safety or efficacy.
Reusable	Yes	Yes	Same
Contact	Non-Contact	Direct Contact	Different: The MIMOSA Imager is a non-contact device while the predicate is not. Other devices within the MUD class, including reference device (Kent Camera, K113507) is non-contacting. In our performance testing, this difference raises no new questions regarding either safety or efficacy.



Power Source	Powered with a rechargeable Li-polymer battery.	AC power-operated with 30-minute lithium-ion battery backup.	Different: The MIMOSA Imager is powered by a lithium-polymer battery certified to IEC 62133 and UN 38.3. This raises no new questions in safety or efficacy.
Measurement Range	1-99% StO ₂	1-99% StO ₂	Same
Display	Attached Android Device Display	Computer console display module	Similar
Materials	Plastic (Nylon 12 / PETG) Enclosure connected to a front-glass, aluminum body smartphone with a PVC cover sheath USB connector cable.	Plastic Enclosure, Metal and Epoxy probe head. PVC cable cover sheath.	Similar
Internal Storage	32000 MB	2000 MB	Similar
Ambient Light	Insignificant contribution to image (relative to NIR LEDs) due to short exposure time	Probe must physically block out all ambient light.	Different: Both devices compensate for ambient light. The MIMOSA Imager uses a short exposure time and a background light compensation algorithm. The predicate device physically attempts to block out light by putting the probe in contact with the imaged tissue. This change in filtering of light had no effect on performance and does not present any additional safety or effectiveness concerns.
Patient Population and Environment	Healthcare environment for patient population with potential circulatory compromise	Healthcare environment for patient population with potential circulatory compromise	Same
Control Method	Android Device controlled	PC controlled	Similar



Sterility	non-sterile	non-sterile	Same
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Performance Testing - Non-Clinical & Clinical

Using NIST-calibrated spectrometer instruments, the device’s LED-system is systematically tested to ensure that it meets tolerances set for illumination wavelength ranges, relative intensity differences between LEDs, as well as overall system endurance. The following core tests are administered on a random sample of our manufactured devices:

- Spectral response to varying amperage
- Transmittance profile, as a function of wavelength
- Stress testing device for endurance, consistency and maximum output

Software documentation and testing have been provided per FDA’s “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.”

Clinical: A comparative study was performed for the MIMOSA Imager and predicate device with side-by-side comparison of clinical performance in order to demonstrate substantial equivalence. The objective of the study was to compare StO2 measurements for MIMOSA Imager and the Vioptix ODISsey in order to demonstrate substantial equivalence between the two devices. In terms of methodology, the study monitor tissue oxygen saturation in the thenar eminence and forearm during a vascular occlusion test (VOT) using both devices. The study population included a total of 39 individuals ranging from 21 to 70 years of age and (1-5) Fitzpatrick skin types. The study results in terms of the 95% confidence interval of the line of best fit narrowly constrains the slope of the line between 0.998 and 1.02. MIMOSA Imager measures were in statistical agreement with Vioptix for thenar eminence and forearm for age between 21-70 and range of Fitzpatrick skin types. The statistical agreement between the two devices support substantial equivalence of MIMOSA Imager and Vioptix, and no adverse events or complications were encountered during or after clinical testing.

Conclusion

The MIMOSA Imager has the same intended use as the predicate, has similar technology that does not raise new types of questions of safety or effectiveness. Bench data demonstrates acceptable accuracy of the MIMOSA Imager with respect to the clinical/industrial gold standard in estimating StO2%. Furthermore, precision data demonstrates substantial equivalence between MIMOSA Imager and the predicate device. Overall, the performance data shows that this device provides reasonable assurance of safety and effectiveness to demonstrate substantial equivalence.

REFERENCES:



[1] Section VI. Specifications: *Ranges and Precision* (Table). T.Ox™ Operator's Manual, ViOptix Inc. (2016). <http://www.vioptix.com/wp-content/uploads/2015/10/OXY-2-USM-1-Rev-I-ViOptix-Tissue-Oximeter-Manual1.pdf>