



December 26, 2018

Mespere LifeSciences Inc.  
Rebecca Li  
Manager of Quality Assurance and Regulatory Affairs  
180 Frobisher Drive, Suite 1C  
Waterloo, N2V 2A2 Ca

Re: K182242  
Trade/Device Name: VO200 - NeurOs Cerebral Oximetry System  
Regulation Number: 21 CFR 870.2700  
Regulation Name: Oximeter  
Regulatory Class: Class II  
Product Code: QEM  
Dated: August 10, 2018  
Received: August 20, 2018

Dear Rebecca Li:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause -S   
Digitally signed by David Krause  
Date: 2018.12.26 12:39:37 -05'00'

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

## Indications for Use

510(k) Number (if known)

K182242

Device Name

VO200 – NeurOs Cerebral Oximetry System

Indications for Use (Describe)

The VO200 – NeurOs Cerebral Oximetry is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain tissue beneath the sensor. The prospective clinical value of data from the VO200 - NeurOs Cerebral Oximetry has not been demonstrated in disease states. The VO200 - NeurOs Cerebral Oximetry should not be used as the sole basis for diagnosis or therapy.

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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**Appendix 5-1**



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K182242

**510(k) SUMMARY**

**Submitted by:** Mespere LifeSciences Inc.  
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Waterloo, Ontario, Canada  
N2V 2A2  
Phone: 519-884-7575  
Fax: 519-884-8810

**Company Contact:** Rebecca S. Li, Manager of Quality Assurance and Regulatory Affairs

**Date Summary prepared:** 8/30/2018

**Trade Name:** VO200 – NeurOs Cerebral Oximetry System

**Common Name:** NeurOs Cerebral Oximetry

**Classification name:** Oximeter, Tissue Saturation (21CFR 870.2700)

**Classification:** Class II Medical Device

**Product Code:** QEM

**Predicate Device:** K082327  
INVOS 5100C Cerebral/Somatic Oximeter System  
Product Code: QEM  
Regulation Number: 870.2700  
This predicate has not been subject to a design related recall

**Intended Use/Indications For Use:**

The VO200 – NeurOs Cerebral Oximetry is intended for use as an adjunct trend monitor of regional hemoglobin oxygen saturation of blood in the brain tissue beneath the sensor. The prospective clinical value of data from the VO200 - NeurOs Cerebral Oximetry has not been demonstrated in disease states. The VO200 - NeurOs Cerebral Oximetry should not be used as the sole basis for diagnosis or therapy.

**Device Description:**

The Mespere VO 200 – NeurOs Cerebral Oximetry System is based on the same optical operating principles of multi-distance diffuse reflectance spectroscopy as the predicate device. It measures oxygenated and de-oxygenated hemoglobin content underneath the sensor probe and allows clinicians to monitor the blood oxygenation level of cerebral tissue.

The VO 200 – NeurOs Cerebral Oximetry System consists of a reusable sensor, a single use disposable adhesive, and a display software. The sensor uses two wavelengths within the range from 660nm to 905nm to measure light absorption of tissue, with one wavelength is more sensitive to deoxygenated hemoglobin, the other is more sensitive to oxygenated hemoglobin. Regional cerebral tissue oxygen saturation is calculated through the ratio of tissue absorption to the two wavelengths and validated against blood sample testing through the blood gas analyzer. Sensors are sized to provide desired depth and area coverage for the measurement.

The sensor consists of LEDs, photo detectors, pre-amplifier, analogue to digital convertor, and a CUP for controlling the light emission and detection sequence, auto power adjustment for LED, gain adjustment for photo detectors to ensure optimized signal to noise ratio, and data processing and calculations. It also has an isolator between the monitor and the sensor to ensure the electric safety of the sensor. The enclosure of the sensor is made of medical grade ABS.

The single use sensor adhesive is made of a soft foam with medical grade adhesives.

The Mespere Display Software can be loaded to a tablet, laptop, or stationary PC. The sensor is then connected through a standard USB connector. It displays the measurement through the computer user interface at a refresh rate of approximately one second. Screenshots of the measurement can be saved to a user specified file and can be exported through USB ports or the internet.

**Technology Characteristics:**

The VO200 - NeurOs Cerebral Oximetry System has the same technology characteristics as the predicate.

Similarities:

- Both are based upon multi-distance, diffuse reflectance, near infrared spectroscopy for analyzing oxygenated and deoxygenated hemoglobin content of blood within cerebral tissue.
- Both use near infrared light emitters (LED) and photo detectors.
- Both uses two near infrared wavelengths

Differences:

- NeurOs sensor probe are reusable, only the medical grade sensor adhesives are one time disposables. The predicate sensor probes are single-use disposables.
- For the predicate sensor, analogue to digital conversion and pre-Amp is made through boxes connected to the probe through cables.

**Comparison Table:**

<b>Characteristics</b>	<b>Mespere VO200 - NeurOs Cerebral Oximetry System (Subject Device)</b>	<b>INVOS 5100C Cerebral/Somatic Oximeter System (Predicate)</b>
<b>Intended Use / Indications For Use</b>	NeurOs Cerebral Oximetry System is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain tissue beneath the sensor.	INVOS 5100C is intended for use as an adjunct monitor of regional hemoglobin oxygen saturation of blood in the brain or in other tissue beneath the sensor.
<b>Target Population</b>	For adult patients.	For adult, pediatric, and neonate patients.
<b>Anatomical Sites</b>	Cerebral	Cerebral
<b>Where used (hospital, home, ambulance, etc.)</b>	Hospital, clinic and other health care facilities	Hospital, clinic and other health care facilities
<b>Technology</b>	near infrared, multi-distance diffuse reflectance spectroscopy, light emitters and photo detectors	near infrared, multi-distance diffuse reflectance spectroscopy, light emitters and photo detectors
<b>Sterility</b>	Non-sterile	Non-Sterile
<b>Calibration</b>	No need	No Need
<b>Features/Method of Use</b>	Non-invasive	Non-Invasive
<b>Monitored parameters</b>	Regional Oxygen Saturation	Regional Oxygen Saturation
<b>Components</b>	- Sensor - Sensor cables - display software - adhesive patch	- Sensor - Sensor cables - Preamplifiers - Monitor
<b>Display</b>	Real-time, continuous	Real-time, continuous
<b>Risks</b>	No compromise to patient care	No compromise to patient care
<b>Optical</b>	Yes  - LEDs and photodetectors	Yes  - LED and photodetector

Characteristics	Mespere VO200 - NeurOs Cerebral Oximetry System (Subject Device)	INVOS 5100C Cerebral/Somatic Oximeter System (Predicate)
<b>Embedded Software</b>	Yes  Integrated software provides analytics for measurements to be displayed	Yes  Integrated software provides analytics for measurements to be displayed
<b>Display</b>	Display StO <sub>2</sub> value (right and left) and trend data graphs	Display rSO <sub>2</sub> values (right and left) and trend data graphs
<b>Probe Attachment</b>	Adhesive to skin	Adhesive to skin
<b>Alarm</b>	No	Yes
<b>Device Type</b>	Needs to be connected to a computer	Standalone Device

**Complied Standards:**

The design of the Mespere VO200 – NeurOs Cerebral Oximetry system conforms to the following voluntary standards:

- EN ISO 13485:2016
- EN ISO 14971:2012
- EN 60601-1:2006/A1:2013
- EN 60601-1-2:2007/AC:2010
- EN 60601-1-6:2010
- EN 62366:2008
- EN ISO 14155:2011
- EN 62304:2006/AC:2008
- EN 1041:2008
- EN 980:2008
- EN 15223-1:2012
- EN ISO 10993-1:2009
- EN ISO 10993-5:2009
- EN ISO 10993-10:2013

**Non-Clinical Tests:**

The VO200 – NeurOs Cerebral Oximetry System was subjected to extensive safety, performance, and verification testing. Extensive benchtop tests verified the performance of the device to meet the design requirements in an ideal non-clinical environment. All tests were performed to ensure that the device complies with industry and safety standards.

**Clinical Tests:**

Clinical tests were performed to verify and validate the clinical performance of the VO200 – NeurOs Cerebral Oximetry system and support the determination of substantial equivalence. The following clinical data was submitted:

**Clinical Validation:** The primary objective of this study was to validate the accuracy of the Mespere VO200 – NeurOs Cerebral Oximetry system for measuring the regional cerebral tissue blood oxygenation saturation (StO<sub>2</sub>), by comparing it to invasive blood samples drawn from the jugular bulb and radial artery, and compared by a co-oximeter. The subjects recruited for this study were healthy volunteers.

**Methods:** With IRB approval and written Informed Consent Forms, healthy volunteers were recruited. An ultrasound-guided small diameter internal jugular vein catheter was inserted and placed at the position of the subject’s superior jugular bulb. A radial arterial line was inserted into a radial artery on the left arm. Two standard pulse oximeters were attached to the patient’s fingers to help guide the hypoxia state plateau levels. The VO200 - NeurOs Cerebral Oximetry sensor was placed on the forehead. Blood gas analysis to determine oxyhemoglobin saturation was performed using a Co-Oximeter. Each subject had control data taken at the beginning of each experiment, with two control blood samples drawn while breathing room air. Hypoxia was induced to different levels of oxyhemoglobin saturation (between 70-100% SpO<sub>2</sub>) by having subjects breathe mixtures of nitrogen, room air, and carbon dioxide. Once a steady state level of hypoxia is achieved, a 1.0ml sample of blood are obtained simultaneously from the jugular line and radial arterial line. A second blood pair of samples, at the same steady-state saturation, is taken 30 seconds later. The VO200 - NeurOs Cerebral Oximetry samples were recorded simultaneously to the blood samples. The blood samples were immediately analyzed by the Co-Oximeter. Up to 27 paired samples were obtained on the plateaus across this span for each subject.

**Results:** The results showed the absolute accuracy of ± 4.9% and trending accuracy of ±1.5% (in range of 40%-80%), which is equivalent or better than the reported absolute accuracy of 5.0% and trending accuracy of ± 4.0 % of the predicate device.

No adverse events were reported.

**Performance specifications**

Parameter	Specification	Notes
StO <sub>2</sub> Measurement Range	0 – 100%	
StO <sub>2</sub> Validated Measurement Range	40 – 80%	1,2,3
Trending Accuracy of StO <sub>2</sub> (40%-80%)	± 1.5%	1,2,3
Absolute Accuracy of StO <sub>2</sub>	± 4.9%	1,2,3



(40%-80%)		
Resolution of StO <sub>2</sub>	1%	

**NOTES:**

- 1** Validation was performed on a measurement range of 40% - 80%
- 2** Accuracy is based on a validation study comparison with venous jugular bulb and radial arterial blood samples and a Co-Oximeter on healthy volunteers. In the StO<sub>2</sub> range of 40-80%, the trending accuracy was ± 1.5% and the absolute accuracy was ± 4.9% in the study STP-9200001 at the University of California San Francisco, UCSF (San Francisco, California, USA).
- 3** **Summary of validation study STP-9200001 at the University of California San Francisco, UCSF (San Francisco, California, USA)**

**Number of Study Sites:**

Primary Clinical Site:

University of San Francisco California (UCSF)

Hypoxia Labs

513 Parnassus Ave.,

San Francisco, CA, 94143-0542

**Subjects/data points:**

The subjects recruited for this study consisted of healthy, non-smoking individuals of age 21-49 years' old who underwent hypoxia testing at the University of California at San Francisco (UCSF) located in San Francisco, California. No subjects was anemic (Hemoglobin ≤ gm·dl-1).

Twelve (12) healthy subjects were recruited for the study. A total of 284 paired venous and arterial blood sample readings, and 284 VO200 - NeurOs Cerebral Oximetry system readings were used to perform the comparison and statistical analysis.

**Patient Demographics:**

Subject	Gender	Age	Skin Tone	Fitzpatrick Skin Tone
Subject #1	Male	26	Olive	IV
Subject #2	Female	25	Medium/light olive	III
Subject #3	Male	26	Medium/light	III

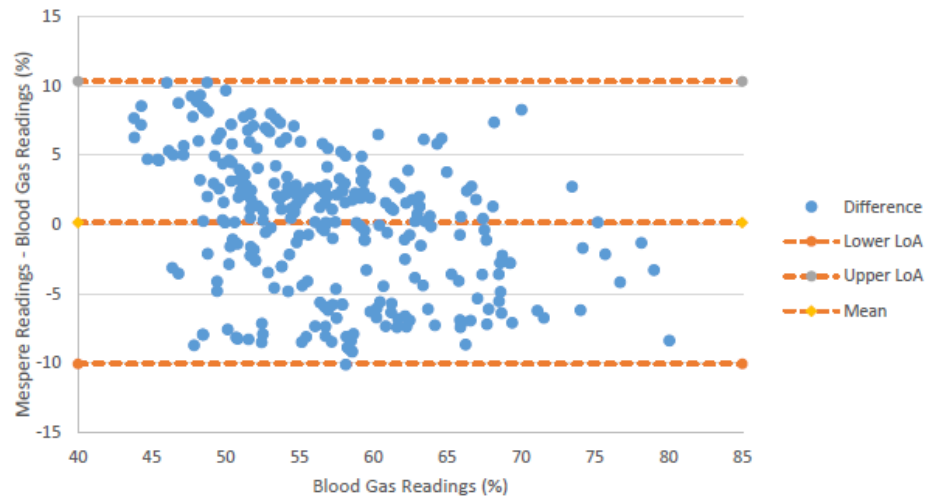
			olive	
Subject #4	Female	33	Fair	II
Subject #5	Male	24	Brown	V
Subject #6	Female	32	Medium/light olive	III
Subject #7	Male	23	Brown	V
Subject #8	Female	23	Fair	II
Subject #9	Male	24	Brown	V
Subject #10	Male	30	Fair	II
Subject #11	Male	31	Fair	II
Subject #12	Male	26	Brown	V

**Agreement Analysis Results:**

The calculated statistical results from the study are as follows:

<b>Trending Accuracy</b>	$\pm 1.5\%$
<b>Absolute Accuracy</b>	$\pm 4.9\%$

***Bland Altman Plot of Absolute Measurement***

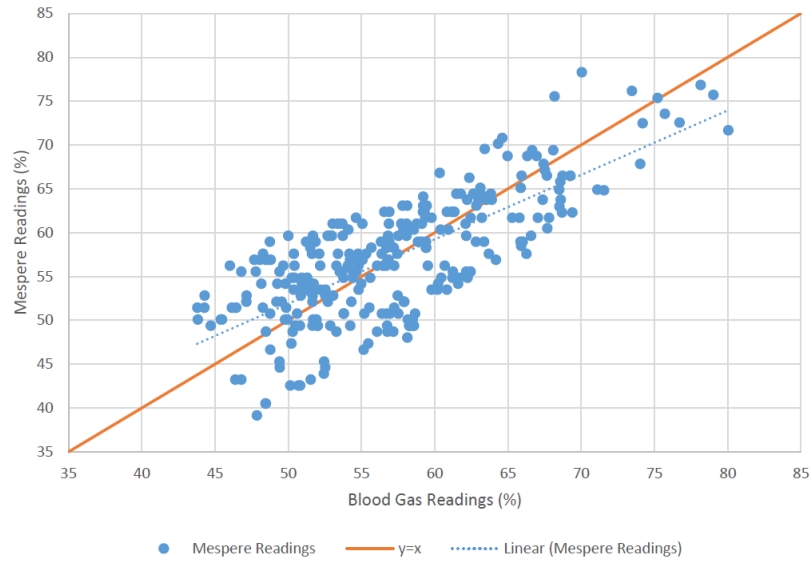


***Linear Regression Analysis of Absolute Measurement with 95% Confidence Interval of Slope and***

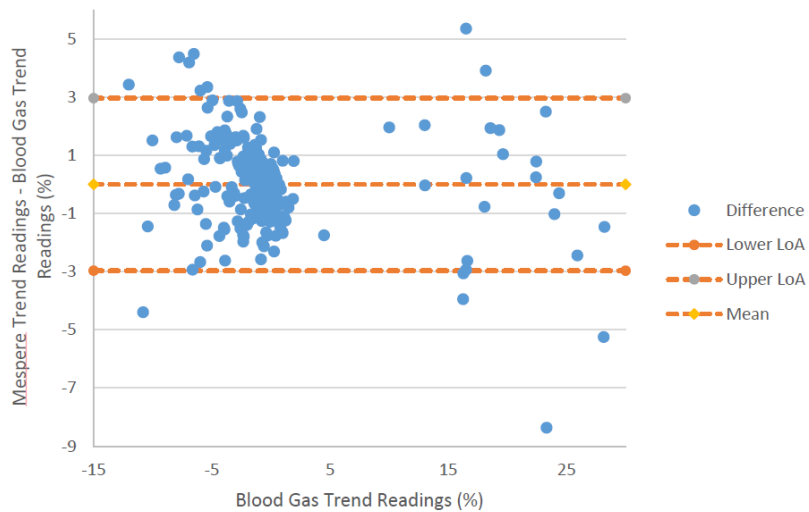
**Intercept using Bootstrap Method**

Slope = 0.7346

Intercept = 15.161



**Bland Altman of Absolute Trending Measurement**



**Linear Regression Analysis of Absolute Trending Measurement with 95% Confidence Interval of Slope and Intercept using Bootstrap Method**



### Conclusions:

The clinical data demonstrates that the VO200 – NeurOs Cerebral Oximetry system is substantially equivalent in performance to the predicate device when measuring regional cerebral tissue blood oxygenation saturation.