MediPines Corporation
Timothy Marcum
Product Engineer
155 N. Riverview Drive
Anaheim Hill, California 92808

Re: K180902
Trade/Device Name: MediPines Gas Exchange Monitor (GEM), Accessory Mouthpiece Disposable Assembly
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK, CCL, BZL, DQA
Dated: December 7, 2018
Received: December 18, 2018

Dear Timothy Marcum:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Todd D. Courtney -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K180902

Device Name
MediPines Gas Exchange Monitor (GEM)

Indications for Use *(Describe)*
The MediPines Gas Exchange Monitor (GEM) is a non-invasive, multi-parameter respiratory monitoring device that provides spot-check respiratory gas measurements of oxygen (PO_2, ETO_2) and carbon dioxide (PCO_2, $ETCO_2$) from breathing, respiration rate (RR), functional saturation of arterial hemoglobin (SpO_2), pulse rate (PR), and a range of other calculated indices.

At-rest patient measurements are obtained in a spot-check measurement session lasting approximately two minutes, using specified accessories which include a single patient use breathing gas mouthpiece, a single patient use nose clip, and a reusable pulse oximeter finger sensor.

The device is indicated for use by qualified medical personnel in professional healthcare facilities on conscious and cooperative patients who are eighteen (18) years and older. The GEM is not to be utilized simultaneously with supplemental Oxygen nor with other respiratory gases or agents.

The MediPines Gas Exchange Monitor (GEM) is not intended to be used as the sole basis for making diagnosis or treatment decisions related to patient gas exchange; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms. It is not intended to replace arterial blood gas sampling for diagnosis or treatment purposes.

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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MediPines Corporation		Document Title **K180902/S001 510(k) Summary**		
Originator **MediPines**	Change Order-	Document Number	Rev	Page **1 of 8**

510(k) Summary in accordance with 21 CFR 807.92

(a) (1) Submitted by:

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Contact Person:

Steve Lee, President
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Date of Preparation:

December 7, 2018

(2) Proprietary or Trade Name:

Gas Exchange Monitor (GEM)

Common/Usual Name(s):

1) Carbon dioxide monitor
2) Oxygen monitor
3) Pulse oximeter

Classification Name(s):

1) 21CFR 868.1400 (Carbon Dioxide Gas Analyzer)
Product Code: CCK
2) 21CFR 868.1720 (Oxygen gas analyzer)
Product Code: CCL
3) 21CFR 870.2700 (Oximeter)
Product Code: DQA
4) 21CFR 870.1730 (Oxygen Uptake Computer)
Product Code: BZL

	K-Number	Model	Manufacturer
(3) Predicate device(s):	**K094012**	Capnostream20	Oridion Capnography, Inc. (now Medtronic)
Reference device(s):	**K093080**	Metaphor Metabolic Monitor	TreyMed, Inc.

Reason for Submission:

New device

(4) Device Description

The Gas Exchange Monitor (GEM) is a non-invasive multi-parameter respiratory monitoring system that uses at-rest spot check breath samples to provide respiratory measurements of oxygen (PO_2, ETO_2) and carbon dioxide (PCO_2, $ETCO_2$) from breathing, respiration rate (RR), functional saturation of arterial hemoglobin (SpO2), pulse rate (PR), and a range of other calculated indices to assess a patient's respiratory status.

The device utilizes a single patient use disposable mouthpiece attached to the monitor via a tubing system and an attached pulse oximetry probe. A nose clip is used during the measurement session. Each session and real-time tracing of breath samples are displayed on the device screen and may be exported as PDF and image files.

(5) Intended Use

As described above, the intended use of the device combines respiratory gas monitor and pulse oximeter functionality and is intended for non-invasive measurement of expired and inspired breathing gases and respiration rate, and for non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. Indices calculated from the breathing gas and pulse oximeter measurements may be used for assessment of patient respiratory status.

Indications for Use:

The MediPines Gas Exchange Monitor (GEM) is a non-invasive, multi-parameter respiratory monitoring device that provides spot-check respiratory gas measurements of oxygen (PO_2, ETO_2) and carbon dioxide (PCO_2, $ETCO_2$) from breathing, respiration rate (RR), functional saturation of arterial hemoglobin (SpO_2), pulse rate (PR), and a range of other calculated indices.

At-rest patient measurements are obtained in a spot-check measurement session lasting approximately two minutes, using specified accessories which include a single patient use breathing gas mouthpiece, a single patient use nose clip, and a reusable pulse oximeter finger sensor.

The device is indicated for use by qualified medical personnel in professional healthcare facilities on conscious and cooperative patients who are eighteen (18) years and older. The GEM is not to be utilized simultaneously with supplemental Oxygen nor with other respiratory gases or agents.

The MediPines Gas Exchange Monitor (GEM) is not intended to be used as the sole basis for making diagnosis or treatment decisions related to patient gas exchange; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms. It is not intended to replace arterial blood gas sampling for diagnosis or treatment purposes.

Discussion of Differences in Indications to the Predicate Devices

The submitted device and referenced predicate device have the following differences in their indication statements:

- The specified patient population for the MediPines Gas Exchange Monitor (GEM), adults at least 18 years of age, is within the scope of claims of the predicate device, which specify adult through neonatal.
- The MediPines Gas Exchange Monitor (GEM) specifies use in spontaneously breathing patients not simultaneously using supplemental Oxygen nor with other respiratory gases or agents. The predicate device may be used for spontaneously breathing or ventilated patients receiving supplemental Oxygen or other respiratory gases or agents. The claims for the subject device are within the scope of the scope of the predicate device.
- The MediPines Gas Exchange Monitor (GEM) intended uses for respiratory gas, S_pO_2, and pulse rate measurements are similar to the predicate device. The physiological parameters directly measured by the MediPines Gas Exchange Monitor (GEM) include Carbon Dioxide and Oxygen by side stream gas measurement including respiration rate (RR) and functional saturation of arterial hemoglobin (S_pO_2) and pulse rate (PR) by pulse oximetry.
    - The predicate Capnostream 20 measures side stream Carbon Dioxide with respiration rate (RR) plus S_pO_2 and pulse rate (PR).
    - The reference Metaphor monitor device measures side stream Oxygen, Carbon Dioxide with respiration rate (RR), and optionally Nitrous Oxide gas plus S_pO_2 and pulse rate (PR).
- The measurement sites for the MediPines Gas Exchange Monitor (GEM) are equivalent to the predicate device: use of side stream gas measurement and a digit (finger for GEM) for pulse oximetry. The side stream measurement of patient breathing gas is equivalent in the subject and predicate device.
- The MediPines Gas Exchange Monitor (GEM) utilizes a single patient use disposable mouthpiece for side stream breathing gas measurement placed in the patient's mouth and the predicate device utilize a disposable airway

adapter for side stream breathing gas measurement which is typically placed in the patient's breathing circuit. The breathing gases obtained are equivalent, including both inspired and expired breath.

- The MediPines Gas Exchange Monitor (GEM) specifies a reusable S_pO_2 sensor type which is applied on the patient's digit (finger sensor). The predicate Capnostream and reference Metaphor monitors make available a range of reusable finger sensors and other sensors, including disposable S_pO_2 sensors. The function and intended use for pulse oximetry is equivalent.
- The MediPines Gas Exchange Monitor (GEM) is defined for spot check use for short duration measurement sessions. The predicate Capnostream 20 is specified for continuous operation, and the referenced Metaphor is specified for spot check or continuous operation. The MediPines Gas Exchange Monitor (GEM) provides no alarms, which is consistent with the use as a spot check device for short duration use.
- The MediPines Gas Exchange Monitor (GEM) and referenced Metaphor are specified for use in professional healthcare facilities. The Capnostream 20 defines both hospital and intra-hospital use environments.

The differences in the wording of the subject and predicate device indications for use are not critical to the intended use of the device as a pulse oximeter sensor and do not affect the safety and effectiveness of the device when used as labeled for the following reasons:

- Slight differences in terminology for the measured parameters are equivalent, i.e. all claims are readily understandable as referring to the respective measurements (example: $ETCO_2$ versus end tidal concentration).
- The MediPines Gas Exchange Monitor (GEM) and the predicate device provide additional calculated numerical indices of pulmonary status based upon mathematical relationships between measured parameters. The Capnostream 20 provides an integrated pulmonary index (IPI) which is a numerical value of overall ventilatory status. Differences in pulmonary indices reported for the devices are accounted for by labeling which describes the indices and the calculations. Both the MediPines Gas Exchange Monitor (GEM) and referenced Metaphor Monitor provide calculated respiratory quotient (RQ).

The differences in the wording of subject and predicate device indications for use are within the scope of the predicate device for the intended use of the subject device as a pulse oximeter and respiratory gas monitor when used as labeled. In summary, the MediPines Gas Exchange Monitor (GEM) has equivalent intended use, or where different, claims which are within those of the predicate device and the reference device, the Capnostream 20 and Metaphor Monitor, respectively.

(6) Technological Characteristics

The MediPines Gas Exchange Monitor (GEM) is designed for the same application and intended use as the listed predicate device, using the same technological principles. Refer to the following comparison tables:

Comparison of Technological Features to Predicate Device

Product/Feature	Gas Exchange Monitor (GEM) (Proposed Device)	Capnostream 20 Capnograph/Pulse Oximeter	Remark
Manufacturer	MediPines Corporation	Oridion Medical Ltd. (now Medtronic)	
Model Number(s)	GEM Model B	20	
510(k) Number	**K180902**	**K094012**	

Product/Feature	Gas Exchange Monitor (GEM) (Proposed Device)	Capnostream 20 Capnograph/Pulse Oximeter	Remark
Intended Use/Application	Multi-parameter monitor including capnography, oximetry; Respiratory gas measurements of oxygen (PO_2, ETO_2) and carbon dioxide (PCO_2, $ETCO_2$) from breathing, respiration rate (RR), Functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate; Calculated pulmonary indices; intended to be used in conjunction with additional methods of assessing clinical signs and symptoms	Combined capnograph/pulse oximeter monitor; Monitoring of carbon dioxide concentration of the expired and inspired breath and respiration rate; Functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate; integrated pulmonary index (IPI) displays a single value that represents the patient's pulmonary parameters. The IPI is an adjunct to, and is not intended to replace, vital sign monitoring.	Subject device use as respiratory gas monitor and pulse oximeter within claims of the predicate device; Measurement of Oxygen in the subject device
Intended Patient Population	Adults eighteen (18) years and older, spontaneously breathing	Neonatal, pediatric, and adult populations; User manual describes spontaneous breathing and ventilated cases	Subject device intended use for spontaneously breathing adults is within the claims of the predicate device
Intended Environment of Care	Professional healthcare facilities only	Hospitals, hospital-type facilities, and intra-hospital transport and home environments	Use of subject device in professional environments is within the scope of the predicate device
Patient Application sites	Patient Mouthpiece (side stream gas measurement) Nose clip Patient finger sensor (SpO2 measurement)	Patient Airway (side stream gas measurement) Patient digit (SpO2 measurement)	Addition of nose clip in subject device does not change intended use for respiratory gas measurement
Alarms	No alarms	Visual and auditory alarms	Use as a non-alarming device is within the scope of the predicate device and consistent with spot-check use
Duration of operation	Short (<5 minute) spot-check sessions; continuous for short duration	Continuous	Subject device use as spot-check device device is within the scope of the predicate device
Supplemental gases	Not to be utilized simultaneously with supplemental Oxygen nor with other respiratory gases or agents	Use with supplemental gases	Use without supplemental gases is within the scope of the predicate device and consistent with spot-check use
Sterility	Non-sterile mouthpiece and reusable SpO2 sensor	Non-sterile airway adapter and reusable SpO2 sensor	Equivalent function
Control System	User interface via PC-based touch screen display. Embedded microcontroller interfaces with gas sensors and pulse oximeter module to obtain measurement data for host	Internal embedded microprocessor	Equivalent functionality
Control Keys	Power Button Touchscreen Display with Virtual keyboard	Monitor Power ON/OFF Event Button Patient Admit/ Discharge Pump Off Temporary Alarm Silence Control Knob	Equivalent functionality

Product/Feature	Gas Exchange Monitor (GEM) (Proposed Device)	Capnostream 20 Capnograph/Pulse Oximeter	Remark
Measurement principle – SpO2	Two wavelength pulse measurement to obtain functional oxygen saturation	Two wavelength pulse measurement to obtain functional oxygen saturation	Same measurement principles
Measurement method – CO2	Sidestream gas sample: Non-dispersive Infrared (NDIR) for CO2 gas	Sidestream gas sample: Non-dispersive Infrared (NDIR) for CO2 gas	Same measurement principles
Measurement method – Oxygen	Sidestream gas sample: galvanic cell for Oxygen sensor	(no galvanic O2 gas measurement)	Subject device includes galvanic O2 measurement (as does reference Metaphor device)
CO2 measurement range	0 – 100 mmHg (0 – 13%)	0-99 mmHg (0-13%)	Equivalent ranges
CO2 measurement accuracy	± 2 mmHg from 0 - 38 mmHg (at ATPS) ± 5% of actual from 39 - 76 mmHg (at ATPS) ± 8% of actual from 77 - 99 mmHg (at ATPS)	± 2 mmHg from 0 - 38 mmHg 39-99 mmHg +/- (5% of reading + 0.08% for every 1 mmHg above 38mmHg)	Equivalent ranges, subject device meets current gas monitoring standard accuracy requirements
O2 measurement range	0 – 800 mmHg (0 – 100%)	N/A	Subject device includes galvanic O2 measurement (as does reference Metaphor device)
O2 measurement accuracy	< ± 1% (at ATPS)	N/A	Subject device includes galvanic O2 measurement (as does reference Metaphor device)
SpO2 measurement range	0 – 99 %	1-100%	Equivalent ranges
Pulse rate measurement range	30 – 254 BPM	25-240 BPM	Equivalent ranges
SpO2 accuracy	± 3% Arms between 70 – 99% < 70% is undefined	70% to 100% +/- 2 digits < 70% is undefined	Equivalent functionality
Pulse rate accuracy	±3 BPM	No motion: +/- 3 digits Motion: +/- 5 digits	Equivalent functionality

Product/Feature	Gas Exchange Monitor (GEM) (Proposed Device)	Capnostream 20 Capnograph/Pulse Oximeter	Remark
Displayed Parameters	**Measured/ Displayed:** CO2 Waveform O2 Waveform Continuous partial pressure of O2 Continuous partial pressure of CO2 End Tidal O2 (PETO2) End Tidal CO2 (PETCO2) Oxygen Saturation (SpO2) Pulse Rate (PR) Respiratory Rate (RR) Pressure of Inspired O2 (PIO2) Pulse Plethysmograph Barometric Pressure **Calculated Indices:** Estimated Arterial O2 (gPaO2) O2 Deficit (Alveolar-arterial O2 difference) Arterial/alveolar oxygen exchange ratio (gPaO2/PAO2) Carrico Index ratio (gPaO2/FiO2) Respiratory Quotient (RQ)	CO2 Waveform ET CO2- End Tidal CO2 FiCO2- Fraction of Inspired CO2 RR- Respiratory Rate SpO2- Oxygen Hemoglobin Saturation PI- Perfusion Index PR- Pulse Rate **Calculated Indices:** IPI- Integrated Pulmonary Index Oxygen Desaturation Index (ODI) Apnea per hour (A/hr)	Equivalent functionality for the pulse oximeter and capnograph values. The MediPines Gas Exchange Monitor (GEM) and predicate device provide additional calculated numerical indices of pulmonary status based upon mathematical relationships between measured parameters. Differences in pulmonary indices reported for the devices are accounted for by labeling which describes the indices and the calculations
Dimensions	Monitor Dimensions: (W x H x D): 267 x 216 x 108 mm	Monitor Dimensions (W x H x D): 220 x 167 x 192	Equivalent functionality, some dimensional differences
Weight	Monitor Weight: 1.7 kg (3.7 lbs)	Monitor Weight: 3.5 kg (7.7 lbs)	Equivalent functionality, some difference in weight
Power	Mains connected device, internal battery	Mains connected device, internal battery	Equivalent functionality
Electrical Protection Class	Type BF	Type BF defibrillation proof	Equivalent functionality, defib not claimed for spot check device
Moisture Protection Class	IPX1	IPX1	Equivalent functionality

In summary, the MediPines Gas Exchange Monitor (GEM) utilizes equivalent technology and has similar technical specifications as the predicate device and the reference device, the Capnostream 20 and TreyMed Metaphor Monitor, respectively.

(b) (1) Non-Clinical Tests Submitted

Compliance Testing

The MediPines Gas Exchange Monitor (GEM) was tested to current applicable standards for medical device electrical safety and electromagnetic compatibility as well as particular standards for pulse oximetry and respiratory gas monitoring. Environmental and mechanical shock and vibration testing was performed with test levels for professional (non-mobile) use. The following standards were utilized in compliance testing:

- IEC 60601-1 Electrical safety
- IEC 60601-1-2 EMC
- ISO 80601-2-55 Performance of respiratory gas monitors
- ISO 80601-2-61 Performance of pulse oximeters

- ISO 10993 Biological testing of medical devices
- ISO 14971 Risk Evaluation
- IEC 62304 Software validation and software lifecycle process

The device met acceptance criteria for compliance to the standards.

Risk Management

Risk and hazard analysis of the MediPines Gas Exchange Monitor (GEM) was performed to the following standard:

- Application of risk management to medical devices per ISO 14971

The device met acceptance criteria for residual risks.

Software Verification and Validation

The MediPines Gas Exchange Monitor (GEM) software was developed in accordance with FDA guidelines for MODERATE level of concern devices. The software lifecycle process was evaluated to meet:

- Medical device software lifecycle process per IEC 62304 with software safety class B (equivalent to MODERATE level of concern).

The device software was verified to requirements and validated to meet the specified intended use(s).

Pulse Rate and Respiration Rate Testing

Test MediPines Gas Exchange Monitor (GEM) was evaluated for pulse rate and respiration rate accuracy per the following standards and guidance:

- Pulse simulator testing of testing of pulse rate per ISO 80601-2-61 and the FDA pulse oximeter guidance
- Respiration testing of testing of respiration rate per ISO 80601-2-55

The device met acceptance criteria for pulse rate and respiration rate accuracy – effects of high respiration rate were noted in device labeling.

Biocompatibility

The single patient use disposable mouthpiece assembly was evaluated for biocompatibility. The tests were performed to the following standards and included the listed tests:

- Biocompatibility testing per ISO-10993-1, ISO-10993-5 and ISO-10993-10
- Cytotoxicity test - MEM elution assay using L-929 mouse fibroblast cells
- Intracutaneous irritation test
- Guinea pig maximization sensitization test

Device patient contact materials met the acceptance criteria for biocompatibility.

The pulse oximeter sensor is a cleared device, with biocompatibility evaluated by the respective manufacturer.

In summary, the device met test criteria for standards conformance to the applicable standards, pulse and respiration rate accuracy, and biocompatibility. Residual risks met criteria for acceptability for the intended use.

(2) Clinical Tests Submitted

Clinical testing was performed under an approved protocol with subject informed consent. Controlled hypoxia test results were obtained in human adult volunteers to validate the accuracy of the pulse oximeter module with specified Adult Soft Tip Finger Sensor versus arterial oxygen saturation (SaO2) as determined by co-oximetry. Clinical test results support device accuracy claims for the specified saturation range.

Clinical studies were conducted on consenting adults to assess the operation of the device in spot check measurement sessions and the calculation of specified indices.

(3) Conclusions from Tests

As described in (b)(1) and (b)(2) above, the MediPines Gas Exchange Monitor (GEM) is equivalent to the predicate device as supported by compliance, laboratory, and clinical testing, and risk management and system level software evaluations as described above.

The results of all tests demonstrate that the MediPines Gas Exchange Monitor (GEM) is substantially equivalent to the referenced predicate device.