November 7, 2024

ExoStat Medical, Inc.
% Georgiann Keyport
Regulatory Consultant
Canopy Regulatory Solutions, Inc.
1073 Falls Curve
Chaska, Minnesota 55318

Re: K212425
Trade/Device Name: MicroTrend System
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: November 4, 2022
Received: November 7, 2022

Dear Georgiann Keyport:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K212425

Device Name
MicroTrend System

Indications for Use *(Describe)*
The MicroTrend is indicated for monitoring oral mucosal PCO2 in adult patients at risk of hemodynamic instability as an adjunct to other standard hemodynamic monitored parameters. This single-use device is indicated for use by qualified medical personnel to assess a patient's peripheral circulation status.

The MicroTrend Monitor provides trending information on tissue POMCO2 readings measured by the disposable sensor every two minutes over a maximum of a continuous 4-hour monitoring period. Additional sensors may be utilized by the clinician for up to 4-hours each until monitoring is deemed unnecessary.

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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510(k) Summary

This 510(k) summary was prepared to provide an understanding of the basis for determining substantial equivalence in accordance with the requirements 21 CFR 807.92.

Submitters Name:	ExoStat Medical, Inc. 14162 Commerce Ave. NE, Suite 100 Prior Lake, MN 55372-1480
Contact Person:	Georgiann Keyport, Official Correspondent
Contact Phone:	(952) 855-4913
Date Summary Prepared:	August 5, 2024
Device Trade Name:	MicroTrend™ System
Common Name:	Carbon Dioxide Gas Monitor
Classification Name:	21 CFR 868.1400, Class II Product Code: CCK
Predicate Device:	K984579, CapnoProbe-A Optical Sensors, Inc. 7615 Golden Triangle Drive, Suite A Eden Prairie, MN 55344

Device Description

The MicroTrend System provides a method of assessing the partial pressure of carbon dioxide (PCO2) in the oral mucosa (POMCO2). The MicroTrend System is a device composed of a Monitor, disposable POMCO2 Sensor, and associated connectors. It is designed to be easy to use with minimum training. A single-use disposable POMCO2 sensor is calibrated and then secured against the inside of the patient's cheek. Once the sensor initiates monitoring, the value of POMCO2 is reported on the MicroTrend Monitor instrument display. The MicroTrend Monitor provides trending information on tissue PCO2 readings measured by the disposable sensor every two minutes over a maximum of a 4-hour continuous monitoring period. Additional sensors may be utilized by the clinician for up to 4-hours each until monitoring is deemed unnecessary.

The MicroTrend System is intended for use as an adjunct to other standard hemodynamic monitored parameters to help interpret the patient condition, treatment, and action by qualified medical professionals.

Intended Use of the Device

The MicroTrend is indicated for monitoring oral mucosal PCO2 in adult patients at risk of hemodynamic instability as an adjunct to other standard hemodynamic monitored parameters. This single-use device is indicated for use by qualified medical personnel to assess a patient's peripheral circulation status.

The MicroTrend Monitor provides trending information on tissue $P_{OM}CO_2$ readings measured by the disposable sensor every two minutes over a maximum of a continuous 4-hour monitoring period. Additional sensors may be utilized by the clinician for up to 4-hours each until monitoring is deemed unnecessary.

Summary of Technological Characteristics

The following table provides a side-by-side comparison of the MicroTrend System to the predicate CapnoProbe-A device.

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Substantial Equivalence Technical Characteristics			
Feature	**MicroTrend™ System (Subject: Under Review)**	**CapnoProbe-A (Predicate: K 984579)**	**Equivalence Comments**
Indications for Use			
Intended Use	Regional oral mucosal tissue PCO2 monitoring.	Regional oral mucosal tissue PCO2 monitoring.	Both devices measure oral mucosal tissue PCO2.
Anatomical Structure of Use	Oral mucosa, specific region Buccal mucosa	Oral mucosa, specific region Sublingual mucosa	Both are oral mucosa with similar tissue and vascularization.
Indicated Patient Population	Adults – hospital patients	Hospital patients	The predicate patient population includes the MicroTrend System patient population.
Indicated Environment of Use	Hospital/ICU setting	Hospital/ICU setting	Same
Prescription Use Only	Yes	Yes	Same
Duration of Use	Intermittent monitoring	Intermittent monitoring	The subject and predicate devices measure PCO2 intermittently; the predicate supports one measurement per sensor, while the subject device supports up to four (4) hours of measurement per sensor.
Condition being diagnosed	Patients at risk of hemodynamic instability	Patients at risk of hemodynamic instability	Same
Single-patient use, disposable sensors	Yes	Yes	Same
Technology Comparison			
Principle of Mucosal pCO_2 measurement	Hydrogen ion detection by Conductance	Hydrogen ion detection by Fluorescence	Both sensors measure positive Hydrogen ions. The hydrogen ions are detected by either a fluorescence change (CapnoProbe-A) or a conductance change (MicroTrend System). Both conductance and fluorescence technologies depend on the sensor cell's hydrogen ion density.
Oral Mucosal pCO_2 results display	Range: 30 to 150 mmHg Resolution: 1 mmHg	Range: 20 to 150 mmHg Resolution: 1 mmHg	Both devices display measured oral mucosal tissue CO_2.

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Substantial Equivalence Technical Characteristics			
Feature	**MicroTrend™ System (Subject: Under Review)**	**CapnoProbe-A (Predicate: K** 984579)	**Equivalence Comments**
Oral Mucosal pCO_2 display units	mmHg or kPa	mmHg or kPa	Same
Calibration required	Yes, before use	Yes, before use	Same
Monitor Power Source	AC Mains Power or Internal Battery	AC Mains Power	Same – Both devices are powered by the AC mains. The MicroTrend System may also be operated on the internal battery for up to four (4) hours.
Electrical Safety Compliance	IEC 60601-1	EN 60601-1	Same
EMC Compliance	IEC 60601-1-2	EN 60601-1-2	Same

As summarized above, the MicroTrend System and the CapnoProbe-A have comparable intended uses, technological characteristics, and specifications.

Non-clinical Performance Tests to Demonstrate Substantial Equivalency
To establish the technical equivalency of the MicroTrend System, bench evaluations were conducted to confirm compliance with performance requirements.

Test	**Description of Evaluations**	**Result**
Package and functional integrity	The packaging and MicroTrend System performances after simulated distribution and at the end of shelf life.	Pass
Biocompatibility evaluations	Cytotoxicity, Intracutaneous Reactivity, Sensitization, and Acute Systemic Toxicity evaluations per ISO10993-5, -10, and -11, respectively.	Pass
Software	Software design, validation, and documentation per the FDA Guidance document: Guidance for the Content of Premarket Submissions for Software Content in Medical Devices.	Pass
EMC, Electrical Safety	MicroTrend System conformance with IEC 60601-1-2:2014 and IEC 60601-1:Edition 3.1 (2012).	Pass
Bench Verification evaluations	Battery operation and recharging, $P_{OM}CO_2$ Sensor Useful life, Operating Environment, $P_{OM}CO_2$ measurement performance, Temperature measurement accuracy (*supporting measurement not displayed*), and Usability analyses.	Pass

Test	Description of Evaluations	Result
System Error Check	Evaluate MicroTrend Sensor design and the error checking function for the MicroTrend System when a MicroTrend Disposable Sensor is subjected to human chewing	Pass
Simulated Bite/Chewing	Assess damage to the MicroTrend Sensor assembly when exposed to typical human biting/chewing forces, and assess the risk of a potential choking hazard.	Pass

Animal Tests to Demonstrate Substantial Equivalency
A swine animal study was conducted to demonstrate the equivalent performance of the MicroTrend compared to the CapnoProbe-A. The $P_{OM}CO_2$ was monitored at baseline after completion of animal preparation, during blood removal for induction of hemorrhagic shock, and during the return of blood removed. The severity of hemorrhagic shock was sufficient to elicit a critical reduction in systemic oxygen delivery, causing systemic lactic acidosis but enabling recovery after the return of blood withdrawn. The analysis focused on determining the ability of the MicroTrend System to recognize the onset of hemorrhagic shock, correlate with its severity, and respond to its reversal.

MicroTrend System performance in the study was demonstrated to be equivalent to the predicate CapnoProbe-A device under experimental conditions of hemorrhagic shock. In the MicroTrend animal study, like the CapnoProbe-A study, the reinfusion of shed blood promptly reversed the hemodynamic abnormalities and reestablished $P_{OM}CO_2$ to near baseline values. This contrasted with a delayed reversal of lactic acidosis.

Clinical Data to Demonstrate Substantial Equivalency
A prospective, non-randomized, single-site historically controlled clinical study was performed to evaluate the Microtrend System performance and compared it to published predicate device data. Oral mucosal tissue PCO_2 ($P_{OM}CO_2$) measurements taken from healthy volunteer subjects using the MicroTrend System with a single-use disposable $P_{OM}CO_2$ Sensor for up to four (4) hours were found to be statistically similar to the historical, combined values obtained from healthy volunteers using the predicate CapnoProbe-A.

The volunteer clinical study results demonstrated no statistical difference between the MicroTrend System and the CapnoProbe-A related to repeatability and reproducibility. These results indicate that the MicroTrend System provides comparable levels of measurement variation to the predicate CapnoProbe-A for assessing tissue PCO_2.

A human factors validation study was conducted, and the MicroTrend System was concluded to be safe and effective for its intended users, uses, and use environments.

Conclusion
The MicroTrend System is substantially equivalent to the predicate device as supported by intended use, bench performance testing, and animal and clinical evaluations without raising different questions of safety and effectiveness.