June 4, 2025

Barbaras Development Inc.
% Paul Dryden
President
ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K251216
Trade/Device Name: 0184 CO2 Sampling line; 0184T CO2 Sampling line; 0139 CO2 Sampling line; 0182 CO2 Sampling line
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: April 16, 2025
Received: April 18, 2025

Dear Paul Dryden:

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)*
K251216

Device Name
0184 CO2 Sampling line; 0184T CO2 Sampling line; 0139 CO2 Sampling line; 0182 CO2 Sampling line

Indications for Use *(Describe)*
The CO2 Sampling lines are the single patient, disposable device intended for monitoring expired gases from the patient.

Environment of use – hospital, sub-acute, and pre-hospital settings.

Patient population – Patients requiring expired gas monitoring.

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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Date Prepared:	16-Apr-25
Sponsor:	Barbaras Development Inc. 3567 OLD CONEJO RD Newbury Park, CA 91320
Sponsor Contact:	Matthew Baile Tel: 805-499-9194 & +86 186 7690 0100
Submission Correspondent:	Paul Dryden ProMedic, LLC
Proprietary or Trade Name:	0184 CO2 Sampling line, 0184T CO2 Sampling line, 0139 CO2 Sampling line, 0182 CO2 Sampling line
Common/Usual Name:	CO2 Sampling Line
Classification Name:	Analyzer, gas, carbon-dioxide, gaseous-phase (accessories)
Product Code:	CCK
Predicate Device:	Tylenol Medical Instruments Co., Ltd - K181981- CO2 sampling line
Common/Usual Name:	CO2 Sampling Line
Classification Name:	Analyzer, gas, carbon-dioxide, gaseous-phase (accessories)
Product Code:	CCK
Reference Device:	ProMedic – Gas Sampling Lines – K023579
Common/Usual Name:	CO2 Sampling Line
Classification Name:	Analyzer, gas, carbon-dioxide, gaseous-phase (accessories)
Product Code:	CCK

Device Description

Barbaras Development Inc. CO2 Sampling lines are the accessories in breathing system and intended for sampling of exhaled gases for monitoring, typically end-tidal CO2.

The Barbaras Development Inc. CO2 sampling lines are used to connect between the patient's end of the breathing system and the distant analyzer, such as the capnograph monitor, along this tube, the patient's breath is continuously sampled. the gas sampling is exhaust only and there is no gas flow back to patient.

The Barbaras Development Inc. CO2 Sampling Lines are a disposable, single patient use that allow to sample of patients exhaled gases. It consists of flexible extruded plastic tubes with and standard connectors on each end. We will present several different configurations like have the filter or without filter in the middle which have been tested and compared to predicates.

The Barbaras Development Inc. CO2 Sampling Lines are offered in the following models: 0184 CO2 Sampling line, 0184T CO2 Sampling line, 0139 CO2 Sampling line, 0182 CO2 Sampling line. Gas sampling devices are not specific to a particular exhaled gas monitor. Almost all gas sampling line are connected to the monitor via a standard luer fitting, whether it is a female or male fitting.

Principle of Operation

The subject device is a gas sampling line that connects between the patient and the sampling monitor. The monitor uses vacuum to pull a small sample of expired gas from the patient through the breathing circuit. It is a conduit for a gas sample to be taken from the patient directly to the gas monitor.

Indications for Use:

The CO2 Sampling lines are the single patient, disposable device intended for use when monitoring patient expired gases.

Environment of use – hospital, sub-acute, and pre-hospital settings.
Patient population – Patients requiring expired gas monitoring.

Patient Population: Patients requiring expired gas monitoring.

Environments of use: Hospital, sub-acute, and pre-hospital settings.

Substantial Equivalence Discussion

The table below compares the key features of the proposed CO2 sampling lines with the identified predicate, K181981 and it demonstrates that the subject devices can be found to be substantially equivalent. The reference device – Gas Sampling Lines – K023579 – has the same size ID as the largest subject device ID. It also lists lines with in-line filter.

In summary, it can be concluded that substantial equivalence is met based on the following discussions:

Indications for Use –
The indications for use are similar for the proposed device when compared to the predicate.
Discussion – Each device is indicated for use sampling expired gases.

Technology and construction –
The design, configurations, shape, size, etc. are equivalent to the predicate and reference.

Discussion of Differences –
The design incorporates a simple means to interface with the patient interfaces with sampling ports such as breathing/ventilator circuit. There are virtually no differences between the proposed devices

and the predicate. Any difference in performance does not raise any different risk concerns compared to the predicate or reference.

Environment of Use –
The environments of use are identical to predicate.
Discussion –There are no differences in the requirements of each environment of use which would raise any new safety concerns when compared to the predicate.

Patient Population –
The patient population of pediatrics to adults is equivalent to the predicate. However, the population is dictated by the gas monitor indications to which the sample line is attached.
Discussion – The patient populations are equivalent to the predicate.

Non-Clinical Testing Summary –
We performed comparative testing of the appropriate performance functions and features.
The tests included:

- Age testing
- Mechanical testing
- Luer Fitting per ISO 80369-7
- Flow / leaks per ISO 80601-2-55
- Strength of bonds
- Tensile Strength

The results show that the subject devices performed equivalent to the predicate. All testing demonstrated that the subject devices are substantially equivalent to the predicate.

Substantial Equivalence Conclusion

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be substantially equivalent.

Table - Comparison of Subject vs. Predicate and Reference Devices

Attributes	Predicate Device Tylenol Medical Instruments Co., Ltd CO2 Sampling line K181981	Subject Device 0184 CO2 Sampling line 0184T CO2 Sampling line 0139 CO2 Sampling line 0182 CO2 Sampling line	Reference Device ProMedic, Inc. Gas Sampling Lines K023579	Comments
Indications for Use	The CO2 Sample Lines are intended to be used where exhaled gas is monitored. The intended population: Patients requiring expired gas monitoring, adult to pediatrics. The intended environment of use: Hospital-OR, sub-acute, and pre-hospital setting.	The CO2 Sampling lines are single patient, disposable device intended for use when monitoring patient expired gases. Environment of use – hospital, sub-acute, and pre-hospital settings. Patient population – Patients requiring expired gas monitoring.	The gas sampling lines are intended to connect from a port in the breathing circuit to the expired gas monitor.	All indicated to provide monitoring of exhaled gases *The reference device is included only for the sampling tube ID specifications.*
Environment of Use	Hospitals and / or sub-acute, pre-hospital	Hospital, sub-acute, clinic, physician offices, pre-hospital	Hospitals and / or sub-acute	Similar
Patient Population	Patient requiring sampling of expired gases	Patients requiring expired gas monitoring, adult to neonates	Not provided	Similar
Duration of Use	Single patient, disposable	Single patient, disposable	Single patient, disposable	Similar
Prescriptive	Yes	Yes	Yes	Similar
Sampling tubing specs	ID – 1.10 mm Length – 2 m	ID – 1.0 and 1.5 mm Length – 3~3.25m	ID – 0.050 inches (1.27mm) and 0.060 inches (1.524 mm) / Length – 8, 10, and 15 feet	The reference device has gas sampling lines cleared slightly above the maximum ID presented for the subject device.
Mode of Operation	Connector to sample from the patient Nasal cannula, nares connector or sampling Port Small bore tubing. Connects to expired gas monitor.	Monitoring exhaled gas via a gas sampling line connected from patient interface with sampling port to capnograph.	Connects to a port in the breathing circuit to the expired gas monitor.	Similar
Gas sampling connection	Luer slip fit or luer lock	Luer slip fit or luer lock	Luer slip fit or luer lock	Similar
Materials	Cannula and tubing - PVC Connectors – Polypropylene, ABS	Tubing - PVC Connectors – Polypropylene, ABS	Tubing – PVC Connectors – Not listed	Similar
Biocompatibility	Indirect contact and direct (skin) contact with the patient ISO 10993 testing	Skin contact: Limited duration of use (< 24 hours) ISO 10993 testing	Not listed	Similar (Note: the gas sampling line is exhaust only and there is

Attributes	Predicate Device Tylenol Medical Instruments Co., Ltd CO2 Sampling line K181981	Subject Device 0184 CO2 Sampling line 0184T CO2 Sampling line 0139 CO2 Sampling line 0182 CO2 Sampling line	Reference Device ProMedic, Inc. Gas Sampling Lines K023579	Comments
	• Cytotoxicity • Sensitization • Irritation	• Cytotoxicity • Irritation • Sensitization		no gas flow back to patient.) Per the 4/6/24 clarification call skin contact was agreed as the only testing needed
Limited duration of use	Less than 24h	Less than 24h	Not listed	Similar
Performance testing	Resistance to flow Tensile strength of connections Luer fitting testing per ISO594-2 Age testing - Environmental Mechanical testing	Back pressure (Resistance to flow) Bond strength (Tensile strength of connections) Luer fitting testing per ISO80369-7 Age testing - Environmental Mechanical testing	Not listed	Performance testing ISO 80369-7 and ISO 80601-2-55