December 16, 2024

Inventeur, LLC
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K240937
Trade/Device Name: AIM
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK, MNK, CAT
Dated: November 19, 2024
Received: November 19, 2024

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.

Submission Number *(if known)*

K240937

Device Name

AIM

Indications for Use *(Describe)*

AIM is a bite block intended for use in patients 18 years and older who require supplemental oxygen and CO2 monitoring during procedures where the patient is expected to be minimally or moderately sedated. AIM is not indicated for use during procedures that are expected to require deep sedation.

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

12-Dec-2024

510k Sponsor:	Inventeur, LLC 16192 Coastal Hwy Lewes, DE 19958
Official Contact:	Tariq Chaudhry Email: tacmd1@gmail.com Phone: 813.843.4408
Submission Correspondent:	Paul Dryden, ProMedic, LLC Paul.Dryden@promedic.cc

Proprietary or Trade Name:	AIM
Common/Usual Name:	Bite block with gas sampling and oxygen delivery
Classification Name:	21 CFR §862.1345 - CCK - Analyzer, Gas, Carbon-Dioxide, Gaseous- Phase 21 CFR §876.1500 - MNK – Endoscopic Bite Block 21 CFR §868.5340 – CAT – Cannula, Nasal, Oxygen
Predicate Device:	Dualguard™ (K140473)
Common/Usual Name:	Endoscopic bite block and nasal oxygen cannula with CO_2 monitoring accessory
Classification Name:	21 CFR §862.1345 - CCK - Analyzer, Gas, Carbon-Dioxide, Gaseous- Phase

1. Device Description

AIM is a single-use, non-sterile bite block with integrated oxygen (O_2) delivery and expired gas sampling tubing for patients undergoing procedures where supplemental oxygen and expired gas sampling is required expired. When paired with an oxygen supply and a capnography monitor, AIM can be left in place after the procedure to deliver oxygen and monitor CO_2 levels.

AIM consists of a bite block, an attached oxygen delivery line and an attached CO_2 sampling line. It delivers oxygen and samples exhaled CO_2 in the oropharynx.

	Subject Device: AIM	Predicate Device: DualGuard™ K140473	Comparison
Indications for use	AIM is a bite block intended for use in patients 18 years and older who require supplemental oxygen and CO2 monitoring during procedures where the patient is expected to be minimally or moderately sedated. AIM is not indicated for use during procedures that are expected to require deep sedation.	DualGuard™ is intended for use in Adult patients who require supplemental oxygen delivery and CO2 monitoring during endoscopy procedures and recovery. The complete device with bite block is to be used during endoscopy procedures. The DualGuard™ Bite Block is to be removed after endoscopy, leaving the O2 delivering/CO2 sampling cannula in place for the patient recovery period.	AIM is not indicated for use during procedures that are expected to require deep sedation. AIM specifies patients greater than 18 years old whereas the DualGuard specifies adult patients. These differences do not result in a new intended use.
Environments of Use	Locations where procedures are performed in which the patient requires supplemental oxygen and monitoring of exhaled gases. Hospitals, Sub-acute facilities, Clinics, Physician offices, MRI, Patient Transport (ambulances, etc.)	Locations where endoscopy procedures are performed in which the patient requires supplemental oxygen and monitoring of exhaled gases.	Similar
Duration of Use	Single patient, disposable	Single patient, disposable	Same
Mode of Operation	AIM is a biteblock that includes methods to deliver oxygen and sample expired gases in the oral cavity.	DualGuard delivers oxygen through a nasal/oral cannula and samples CO2 nasally and orally.	Similar: Both devices are placed in the mouth and serve as bite blocks that deliver oxygen and monitor CO2 in the oral cavity. AIM does not include an integrated nasal cannula.

	Subject Device: AIM	Predicate Device: DualGuard™ K140473	Comparison
Biocompatibility	Surface contact, skin and mucosal. Externally communicating, tissue. Limited use (<24hr)	Surface contact, skin and mucosal. Externally communicating, tissue. Limited use (<24hr)	Similar patient contact and duration of use
% Fraction of Inspired O2 (FiO_2)	Comparative testing of simulated oxygen delivery was completed at several respiratory rates, tidal volumes, and oxygen flow rates.		AIM maintained FiO2 equivalent to the predicate device in all simulated conditions.
% End Tidal CO2 ($EtCO_2$)	Comparative testing was completed under two simulated conditions at multiple simulated $EtCO_2$ values.		AIM indicated EtCO2 is equivalent to the predicate device in all simulated conditions.
CO_2 Waveforms	Comparative testing was completed under several simulated respiratory conditions, oxygen flow rates, and simulated $EtCO_2$ values.		AIM captured CO_2 waveforms as well as or better than the predicated device in all simulated conditions
Target population	>/= 18 y.o.	Adult	Similar
Connectable to capnograph?	Yes	Yes	Same
Expired gas sampling location	Oral – multiple ports	Nasal and Oral	Similar
Design	Bite block with attached oxygen delivery tubing which delivers oxygen to the back of the mouth. Multiple sampling ports which are connected to a gas sampling line which is attached a capnograph	Oval shape inserted into the mouth with a central opening for insertion of instruments. Includes sampling nasal cannula and oxygen delivery tubing. It has an elastic head band	Both design include means for delivering oxygen and sampling CO2 and method of securement.
Location of use	Inserted on either the left or right side of the mouth	Inserted in the center of the mouth	The differences do not raise a different question of safety and effectiveness.
Mechanism for securement	AIM inserted into mouth and secured with tape	Secured with an elastic band around the head	Each has a means of securing from potential dislodgement

3. Substantial Equivalence

AIM is considered substantially equivalent to the predicate DualGuard device based on the following discussion.

AIM has a similar intended use as the predicate device. AIM specifies patients greater than 18 years old whereas the DualGuard specifies adult patients. This difference does not affect the risk profile of the device.

DualGuard device supplies oxygen and samples CO_2 through the nose and mouth, while AIM delivers oxygen and samples CO_2 for capnography in the oropharynx. During testing, AIM delivered oxygen and sampled CO_2 for capnography as effectively as the DualGuard device over a broad range of oxygen flow rates, simulated end-tidal CO_2 levels, tidal volumes, and respiratory rates. Both devices are used with standard oxygen sources and capnography machines.

Neither device is life-supporting or life-sustaining.
AIM and DualGuard have similar intended use and technological characteristics. The differences between the two devices do not raise additional questions of safety and effectiveness.

4. Summary of Testing

AIM has been evaluated according to the standards listed in the table below. $EtCO_2$ and FiO_2 tests were performed at a range of respiratory rates, tidal volumes, and oxygen flow settings. All AIM samples passed the non-clinical tests, and all samples passed the performance tests at least as well as the predicate device.

Test	Standard / Pre-determined Acceptance Criteria
Biocompatibility	ISO 10993-5:2009 ISO 10993-23:2021 ISO 10993-10:2021 ISO 18562-2:2017 ISO 18562-3:2017
Performance Tests (FiO2, EtCO2) including CO2 waveforms	Comparison to predicate
Mechanical Tests (Bite Force Finite Element Analysis, Dislodgement Force, Axial Separation Force)	Minimal deformation Comparison to predicate ISO 80369-2
Accelerated aging	Comparison of pre and post-aging ISO 80369-2 ISO 594-2 ISO 11607-1
Ship Testing	ISTA 3A

5. Conclusion

The testing and comparison to the predicate support a decision of substantial equivalence.