December 23, 2021

Meditera Tibbi Malzeme San Ve TIC AS
℅ Paul Dryden
Consultant
Meditera Tibbi Malzeme San Ve TIC AS c/o ProMedic LLC
131 Bay Point Dr NE
St. Petersburg, Florida 33704

Re: K210992
Trade/Device Name: Exhalation Valve (Single Limb, Dual Limb)
Regulation Number: 21 CFR 868.5870
Regulation Name: Nonrebreathing Valve
Regulatory Class: Class II
Product Code: CBP
Dated: November 22, 2021
Received: November 24, 2021

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 (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/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 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 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,

Brandon Blakely
Assistant Director
DHT1C: Division of Sleep Disordered
Breathing, Respiratory and
Anesthesia 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210992

Device Name
Altech® Exhalation Valve (Single Limb and Dual Limb)

Indications for Use *(Describe)*
The exhalation valves are intended to be used in ventilator circuits consistent with the indicated use of the ventilator to which they are attached.

The single limb model directs flow and allows for pressure monitoring and may be used within hospitals and for home care use.

The dual limb model regulates flow and is for use in hospitals and for home care use.

The exhalation valve are used with adults, pediatrics, and neonates.

The exhalation valves are for single patient use and can be used for a maximum of 30 days

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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510(k) Summary

Date Prepared:	22-Dec-21
Sponsor:	Meditera Tıbbi Malzeme San. ve Tic. A.Ş. İbni Melek OSB Mah. TOSBİ Yol 4 Sok No: 29 Tire Organize Sanayi Bölgesi Tire / İzmir / Turkey Cenk Kılıç Kalkan, Quality Manager T: +90 232 513 51 10
Submission Correspondent:	Paul Dryden ProMedic, LLC 131 Bay Point Dr NE St. Petersburg, FL 33704
Proprietary or Trade Name:	Altech® Exhalation Valves (Single Limb and Dual Limb)
Regulation Number: **Regulation Name:** **Product code:**	21 CFR 868.5870 Non-rebreathing Valve CBP
Predicate Device: **Manufacturer:** **Regulation Number**: **Regulation Name:** **Product code:**	Exhalation valve - K132143 Intersurgical 21 CFR 868.5870 Non-rebreathing Valve CBP

Device Description:
The Altech® Exhalation Valves (Single Limb and Dual Limb) are available in 2 configurations intended for use in Single and Dual Limb ventilator circuits. The difference between the configurations is location of exhaust of the expired gas to the room. In the Single limb, the valve is integrated to the limb and expired gas exhausts through the opening below the valve whereas in the dual limb the valve is attached to the end of the exhalation limb and the expired gas exhausts through device end of the valve.

Principle of Operation:
Exhalation Valves have control line (L port) which passes the pressure from the ventilator to open or close the internal valve.

When starting to deliver an inspiratory breath, the ventilator pressurizes the exhalation valve, closing the exhalation path so that the positive pressure is delivered to the patient. At the end of inspiration, the pressure releases, the Exhalation valve gas pathway opens and the patient's exhaled gases then are vented to the room through the exhalation limb from device end of the valve for dual limb circuits or exhausted through the bottom opening of the valve for the single limb circuit.

Indications for Use:
The exhalation valves are intended to be used in ventilator circuits consistent with the indicated use of the ventilator to which they are attached.

The single limb model directs flow and allows for pressure monitoring and may be used within hospitals

and for home care use.

The dual limb model regulates flow and is for use in hospitals and for home care use.

The exhalation valve are used with adults, pediatrics, and neonates.

The exhalation valves are for single patient use and can be used for a maximum of 30 days

Patient Population:
Adult, Pediatric and Neonates on mechanical ventilation.

Environments of use:
They may be used with ventilators that are indicated for hospital and / or home settings. In all cases the Exhalation valves are part of the ventilator circuit and would be consistent with the indications of the ventilator to which they are attached.

Difference Between Subject and Predicate

Table 2 below presents the differences between the subject device and the predicate which are:

- Indications for use include the addition of neonate population and adding a Dual limb model in addition to the single limb model
- The technological characteristics are similar between the subject device and the predicate in that they both use a valve which opened or closed by pressure that is applied by the ventilator. The only difference is that the predicate does not offer a dual limb design which connects to a dual limb circuit thus directing expired gases to the ventilator whereas the single limb design for both devices exhausts the expired gases to the room as they connect to a single limb circuit.
- Performance and Specifications are similar and the differences in expiratory resistance and leakage are within acceptable ranges
- Patient population of adding Neonates
    - The use of the subject device is dependent upon the ventilator to which it is attached and its indications for use.

Non-clinical Performance Data

Non-clinical performance testing is summarized in the below table.

Table 1 – Summary of Non-clinical Testing

Test Methodology	Purpose	Results
ISO 5356-1	Conical fittings for 15 / 22 mm Testing was performed pre- and post-aging and after 30 days use and after storage conditions	Fittings were tested according to ISO 5356-1 and meet the performance criteria
ISO 5367	Leakage Testing was performed pre- and post-aging and after 30 days use and after storage conditions	Leakage of <70 ml/min
	Resistance to Flow	Adult <0.06 cmH2O/l/m

	Testing was performed pre- and post-aging and after 30 days use	Pediatrics < 0.12 cmH2O/l/m Neonate < 0.74 cmH2O/l/m
Storage condition and testing post-aging	Evaluate performance after exposure to various storage conditions and post-aging	Met the predefined performance criteria
Performance after 30 days	Evaluate performance after 30 days continuous use	Testing of leakage, resistance to flow met the acceptance criteria per each standard
Performance under various ventilator modes	To evaluate performance when used in various ventilator modes	Testing over different ventilator modes was performed to confirm the compatibility of the device with a ventilator
ISO 10993-5	Evaluate materials for cytotoxicity	Found non-cytotoxic
ISO 10993-10	Evaluate materials for sensitization and irritation	Non-sensitizer Non-irritant
ISO 10993-11	Evaluate materials for Material Mediated Pyrogenicity and Acuta Systemic Toxicity	Non-pyrogenic Non-toxic
ISO 18562-2	Particulate Material	Met the predefined acceptance criteria
ISO 18562-3	Evaluate Volatile Organic Chemicals	Toxicological Risk Assessment resulted in Margin of Safety >1

The testing demonstrated the performance of the subject device to the above listed standards.

Comparative testing to the predicate as discussed in Table 2 below demonstrate the 2 devices to be substantially equivalent in performance, technological characteristics, principles of operation and indications for use.

Substantial Equivalence Conclusion
The conclusions drawn from the nonclinical tests demonstrate that the Altech® Exhalation Valve (Single Limb and Dual Limb) demonstrate substantially equivalent to the predicate.

Table 2 – Comparison – Subject vs. Predicate

	Subject Device Altech® Exhalation Valves (Single Limb and Dual Limb) Models	Predicate Device (K132143) Intersurgical Exhalation valve	Comparison
Classification	Product Code – CBP CFR 868.5870 Classification – Non-rebreathing Valve	Product Code – CBP CFR 868.5870 Classification – Non-rebreathing Valve	Similar
Indications for Use	The exhalation valves are intended to be used in ventilator circuits consistent with the indicated use of the ventilator to which they are attached. The single limb model directs flow and allows for pressure monitoring and may be used within hospitals and for home care use. The dual limb model regulates flow and is for use in hospitals and for home care use. The exhalation valve are used with adults, pediatrics, and neonates. The exhalation valves are for single patient use and can be used for a maximum of 30 days.	The exhalation valves are used to control Inspiratory pressure and expel the expired air from a patient being ventilated via a single limb breathing system. The exhalation valve and single limb breathing systems are used with adults/pediatrics and prescribed by a Physician. A pediatric population is defined as 10 kg to 40 kg in weight. The product is not for use in neonates. The device can be used within hospitals and for home care use. It is a single patient use device and can be used for a maximum of 30 days.	The subject has models for use in both single and dual limb circuits. Added neonates. Otherwise they are similar.
Patient pollution	Adult / Pediatric / Neonates	Adult / Pediatric	Similar except the subject can be used with neonates if the ventilator to which it is attached is so intended
Environment of Use	Hospital and home consistent with the ventilator to which they are attached	Hospital and home	Similar
Fundamental scientific technology	Place in-line with ventilator circuit, pressurized by ventilator to open / close to direct flow	Place in-line with ventilator circuit, pressurized by ventilator to open / close to direct flow	Similar
Disposable	Single patient, disposable up to 30 day use	Single patient, disposable up to 30 day use	Similar
Non-sterile	Yes	Yes	Similar

	Subject Device Altech® Exhalation Valves (Single Limb and Dual Limb) Models		Predicate Device (K132143) Intersurgical Exhalation valve	Comparison
Design Performance				
Resistance to Flow (cmH_2O)	Dual Inspiration (placed on the expiration side only) @ 30 Lpm – 0 @ 15 Lpm – 0 @ 2.5 Lpm – 0 Expiration @ 30 Lpm – 1.95 @ 15 Lpm – 1.36 @ 2.5 Lpm – 0.80	Single Inspiration 0.03 0 0 2.35 1.17 0.48	@ 30 Lpm – 0.9 @ 10 Lpm – 0.6	Similar Subject device included testing for neonate. The predicate as a Single limb there is no difference between inspiratory and expiratory limbs. The Dual limb configuration is placed on the exhalation side of the circuit.
Leakage in main body ml/min	6	2	<0.5	The difference in leakage is compensated by the ventilator and does not raise new risk concerns
Pressure Ratio	1:3		1:1.5 and 1:2	Similar
As Patient connection ISO 5356	22 mm / 22/15 mm		22 mm / 22/15 mm	Similar
Shelf-life	3 years		5 years	Similar
Storage testing	-20°C to +50°C		-20°C to +50°C	Similar
Inspiratory Trigger	1 to 9 for pressure and volume control setting		< 30 ms	Similar
Expiratory trigger	1 to 9 Pressure		Not specified	Similar

	Subject Device Meditera Tibbi Exhalation Valve Dual / Single Limb Models	Predicate Device (K132143) Intersurgical Exhalation valve	Comparison
Biocompatibility	ISO 10993-5 - Cytotoxicity ISO 10993-10 – Sensitization and Irritation ISO 10993-11 – Material Mediated Pyrogenicity ISO 18562-2 – Particulate Material ISO 18562-3 – Volatile Organic Chemicals Toxicology Risk Assessment Biological Evaluation	ISO 10993 details not listed	Similar All applicable tests were performed for the type of patient contact