July 20, 2018

Bio-Med Devices, Inc.
% Paul Dryden
Consultant
ProMedic, LLC
61 Soundview Road
Guilford, Connecticut 06437

Re: K173973
Trade/Device Name: Tv-100
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: June 20, 2018
Received: June 21, 2018

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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,

James J. Lee -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 on last page.

510(k) Number *(if known)*

K173973

Device Name

TV-100

Indications for Use *(Describe)*

The TV-100 is intended for use by qualified medical personnel to provide intermittent to continuous ventilatory support to neonatal, pediatric, and adult patients. The TV-100 is intended for use in both invasive and non-invasive ventilation modes. The TV-100 is intended for use in hospital including intra-hospital transport, pre-hospital, and air transport settings.

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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Bio-Med Devices
61 Soundview Road
Guilford, CT 06437

Tel (203) 458-0202

Official Contact: Kenneth Close – Regulatory Affairs Manager

Proprietary or Trade Name: TV-100

Common/Usual Name: Ventilator, continuous, facility use

Classification Name/Code: CBK - ventilator, continuous, facility use
21CFR 868.5895
Class II

Device Name: TV-100

Predicate Device: K942938 – Bio-Med Devices CrossVent-4
Reference Device: K140939 **–** Hamilton T-1

Device Description:
The TV-100 is designed to be a compact, lightweight, microprocessor controlled ventilator which allows for precise ventilatory control. The TV-100 features an internal compressor which allows the TV-100 to operate without the need for external pressurized gas supplies; however an external oxygen supply may be connected to blend with the air from the internal compressor. To further simplify use there are minimal ventilation controls. The TV-100 user interface (UI) is a touchscreen color LCD with full VGA resolution.

The TV-100 ventilator is a DC powered device operating on internal lithium ion batteries and powered by an external IEC 60601-1 compliant power supply. The external supply also charges the batteries.

Ventilation Modes include:
A/C Mode (Assist/Control)
CPAP Mode (Continuous Positive Airway Pressure)
NIV Bilevel Mode (Non-invasive Ventilation)
SIMV Mode (Synchronized Intermittent Mandatory Ventilation)
PRVC Mode (Pressure Regulated Volume Control)
Constant Flow
Apnea Detection
Standby Mode

Indications for Use:
The TV-100 is intended for use by qualified medical personnel to provide intermittent to continuous ventilatory support to neonatal, pediatric, and adult patients. The TV-100 is intended for use in both invasive and non-invasive ventilation modes. The TV-100 is intended for use in hospital including intra-hospital transport, pre-hospital, and air transport settings.

Patient Population
Neonates, pediatrics, and adults.

Environment of Use:
Hospital including intra-hospital transport, Pre-hospital, and Air Transport settings.

Predicate and Reference Device Comparison:
We compared the Bio-Med Devices TV-100 to the predicate device: Bio-Med Devices - CrossVent 4 - K942938 and the reference device Hamilton T-1 – K140939.

Substantial Equivalence Discussion of Comparison to Predicate and Reference
The Bio-Med Devices TV-100 is viewed as substantially equivalent to the predicate and reference devices because:

Indications –

Indications for use are to provide intermittent to continuous ventilatory support to neonatal, pediatric, and adult patients. For use in both invasive and non-invasive ventilation modes.
Discussion – These are similar indications for use of the predicate – Bio-Med Devices - CrossVent 4 - K942938, except for non-invasive ventilation. These are similar indications for use to the reference – Hamilton T-1 – K140939.

Technology –

The technology of a turbine based portable ventilator is similar to the predicate.
Discussion – The technology and principle of operation for the proposed device is similar to the predicate – Bio-Med Devices - CrossVent 4 - K942938 and reference Hamilton T-1 – K140939.

Environment of Use –

The environment of use – hospital and intra-hospital transport, pre-hospital and aircraft transport setting are similar to the predicate and reference.
Discussion – The environments of use are similar to the reference – Hamilton T-1 – K140939.

Patient Population –

The patient population of neonates to adults is similar to both the predicate and reference.
Discussion – The patient population is identical to the predicate – Bio-Med Devices - CrossVent 4 - K942938 and reference Hamilton T-1 – K140939.

Modes of Ventilation and Specifications –

The modes of ventilation are similar to both the predicate and reference. In addition, a comparison of the specifications and operating ranges are similar as well.
Discussion – All ventilation modes, except NIV, are similar to the predicate – Bio-Med Devices - CrossVent 4 - K942938. For NIV mode the reference – Hamilton T-1 – K140939 has this mode as well as all the modes of ventilation of the proposed device.

Non-Clinical Performance Testing Summary

Biocompatibility / Materials –

The materials which are in the gas pathway have been evaluated via Gas emission VOC, Inorganic gases (CO, CO_2, Ozone), and $PM_{2.5}$ testing with a risk based assessment. No materials are in a humidified gas pathway.

Discussion – The materials were found to be biocompatible for the intended use, intended population and type of patient contact.

Performance Testing –

The device has been tested to insure that all requirements have been met, this includes:

- Testing for compliance with ISO 80601-2-12
  - Gas Compatibility Requirement
  - Alarm, Power Supply Failure
  - Alarm, Internal Power Supply
  - Volume Control Accuracy
  - Pressure Control Accuracy
  - Oxygen Response Time
  - Alarm, Oxygen
  - Accuracy, Airway Pressure
  - Alarm, Low Volume Conditions
  - Alarm, VTE LTE 50 ml
  - Maximum Pressure Limiting
  - Alarm, High Pressure
  - Alarm, PEEP High Limit
  - Alarm, Obstruction Condition
  - Alarm, Partial Occlusion
  - Single Fault Conditions
  - Failure, One Gas Supply
  - Single Fault Tolerance
  - Delivered Oxygen Concentration
  - Accessory Compliance Testing
  - Gas Mixer per 11195
  - Leakage, Unintended
  - Breathing, Loss of Power Supply
  - Signal IO Disruption
  - Expiratory Pause
  - Inspiratory Pause
  - Global Alarm Off Prevention
  - Alarm Condition, Audio Paused
  - Trigger sensitivity
- Testing in accordance with ASTM F1100-90
- Usability testing
- Endurance Testing
- Comparative Waveform Testing
- Shock and Vibration Testing
- DO-160 testing
- RFID following AIM standard

- Drop, vibration and environmental temperature and humidity, and altitude for the applicable environments of use

In addition the device has also been tested to the requirements of the following standards:

- AAMI / ANSI ES60601-1:2005 + A1: 2012 Medical electrical equipment - part 1: general requirements for basic safety and essential performance
- IEC 60601-1-2: 2007 Collateral standard: Electromagnetic Compatibility - Requirements and Tests
- IEC 60601-1-8: 2012 Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- ISO 80601-2-12: 2011 Particular requirements for the safety of lung ventilators - Critical care ventilators
- ASTM F1100: 2004 Standard Specification for Ventilators Intended for Use in Critical Care

Discussion – The results of the testing demonstrated that the TV-100 comply with the applicable requirement of both standards as well as performed within it performance specifications that are substantially equivalent to the predicates – Bio-Med Devices - CrossVent 4 - K942938 and Hamilton T-1 – K140939.

Usability –
We performed a usability study with 16 qualified users.
Discussion – The usability demonstrated that the TV-100 can be used by the intended users as intended.

Discussion of Differences
The basic design, indications for use, patient population, and environments of use, technological characteristics, ventilation modes, alarms, performance specifications and features of the TV-100 are similar to both the predicate and reference – Bio-Med Devices - CrossVent 4 - K942938 and Hamilton T-1 – K140939.

There are no notable differences in the performance range which would raise any new risks or safety concerns.

Device Comparison

Attribute	Proposed TV-100	Primary Predicate Bio-Med Devices - CrossVent -4 K942938	Reference Hamilton -T-1 K140939
Product Code	CBK	CBK	CBK
Intended Use	The TV-100 is intended for use by qualified medical personnel to provide intermittent to continuous ventilatory support to neonatal, pediatric, and adult patients. The TV-100 is intended for use in both invasive and non-invasive ventilation modes. The TV-100 is intended for use in hospital including intra-hospital transport, pre-hospital, and air transport settings.	The CV4 is intended for use by qualified medical personnel to provide intermittent to continuous ventilatory support to neonatal, pediatric, and adult patients. The TV-100 is intended for use in both invasive and non-invasive ventilation modes. The CV4 is intended for use in hospital, intra-hospital transport and pre-hospital transport settings. *Note there was not a FDA published IFU statement*.	The HAMILTON-T1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.
Patient population	Neonate, pediatric, adults	Neonate, pediatric, adults	Neonate, infant, pediatric, adults
Environment of use	Hospital, intra-hospital transport Pre-hospital Air transport settings	Hospital, intra-hospital transport Pre-hospital	Hospital, intra-hospital transport Pre-hospital Air transport settings
Modes of Operations			
Assist / Control	Yes	Yes	Yes
SIMV	Yes	Yes	Yes
CPAP	Yes	Yes	Yes
Pressure support	Yes	Yes	Yes
Sigh	Yes	Yes	Yes
Continuous Flow	Yes	Yes	Yes
Pressure Limit	Yes	Yes	Yes
NIV Bi-Level	Yes	No	Yes
Delivered Parameter Ranges			
Peak Pressure	3-100 cmH_2O	0-120 cmH_2O	60 cm H_2O
PEEP Pressure	0-35 cmH_2O	0-35 cmH_2O	0-35 cmH_2O
Pressure Support	1-60 cmH_2O	0-50 cmH_2O	0-60 cmH_2O
Oxygen %	21-100%	21-100%	21-100%
Breath Rate (bpm)	5-150 BPM	5-150 BPM	5-150 BPM
Tidal Volume	2-2500 mL	5-2500 mL	2-2000 mL

Attribute	Proposed TV-100	Primary Predicate Bio-Med Devices - CrossVent -4 K942938	Reference Hamilton -T-1 K140939
Inspiratory Time	0.10-3.0 sec	0.10-3.0 sec	0.1-12.0 sec
I/E Ratio	3:1 to 1:99	3:1 to 1:99	1:9 to 4:1
Flow Rate	0.1-180 LPM	1-120 LPM	up to 260 l/min
Pressure Trigger	-0.2 to -10 cmH_2O	-0.2 to -10 cmH_2O	N/A
SIMV Rate	0.6-50 BPM	0.6-50 BPM	5 to 80 b/min
SIGH	Up to 130% of set volume or +10 cm H_2O	0-2500 mL	Every 50 breaths at +10 cm H_2O
Alarms			
Peak Pressure	YES	YES	Yes
Rate	YES	YES	Yes
Oxygen	YES	YES	Yes
PEEP / CPAP	YES	YES	Yes
Mean Pressure	YES	YES	Yes
Low Battery	YES	YES	Yes
Low Supply Pressure	YES	YES	Yes
Exhaled Tidal Volume	YES	YES	Yes
Exhaled Minute Volume	YES	YES	Yes
Technology			
Software driven	Yes	Yes	Yes
Gas source	Turbine	Turbine	Turbine
Physical Specifications			
Dimensions	12.8” x 11.9” x 7.9”	10” x 11” x 5.5”	9.4” x 8.3” x 12.2”
Weight	7 kg	4.8 kg	14.3 kg with battery
Operating Temperatures	0 to 40ºC	0 to 40ºC	-15 to 50ºC
Storage Temperatures	0 to 50ºC	0 to 50ºC	-20 to 60ºC
Electrical Power Source	90 to 264 V AC Back-up battery	100 to 240 V AC Back-up battery	100 to 240 V AC Back-up battery
Battery time	7 hr	6 hr	8 hr
Maximum Safety Pressure	81-119 cm H_2O adult 49-71 cm H_2O neonatal	98 to 142 cm H_2O	70 cm H_2O
Pneumatic Power Source	Air / Oxygen	Air / Oxygen	Air / Oxygen
Audible Alarm characteristics	83 dB min @ 10cm	83 dB min @ 10cm	Not specified

Clinical Testing Summary:
No clinical testing was performed

Substantial Equivalence Conclusion
The Bio-Med Devices TV-100 ventilator is substantially equivalent to the above listed predicate and we have determined that there are no significant differences which would affect safety and efficacy for the patient population. This has been demonstrated through performance testing, design, and features, and non-clinical testing.