August 2, 2019

Hamilton Medical AG
Annemarie Weideli
Quality Engineer
Via Crusch 8
Bonaduz, 7402 Ch

Re: K181216
Trade/Device Name: Hamilton-C1, Hamilton-T1
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK, DQA
Dated: November 7, 2018
Received: November 13, 2018

Dear Annemarie Weideli:

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,

James Lee, Ph.D.
Assistant Director
DHT1C: Division of ENT, 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: 08/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181216

Device Name
HAMILTON-C1

Indications for Use *(Describe)*
The HAMILTON-C1 ventilator is intended to provide positive pressure ventilatory support or continuous flow of respiratory gases to adults and pediatrics, and optionally infants and neonates.

Intended areas of use:
• In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room
• During transfer of ventilated patients within the hospital

The HAMILTON-C1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 below.

510(k) Number *(if known)*
K181216

Device Name
HAMILTON-T1

Indications for Use *(Describe)*
The HAMILTON-T1 ventilator is intended to provide positive pressure ventilatory support or continuous flow of respiratory gases to adults and pediatrics, and optionally infants and neonates.

Intended areas of use:
- In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room
- For emergency medical care
- During transport within and outside the hospital
- During transfer by rescue vehicles, fixed wing aircraft, helicopter or ship

The HAMILTON-T1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

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)

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HAMILTON MEDICAL
Intelligent Ventilation since 1983

HAMILTON-C1
HAMILTON-T1

510(k) SUMMARY

I. SUBMITTER:

Hamilton Medical AG
Via Crusch 8
Bonaduz, 7402
SWITZERLAND

Phone: +41 58 610 15 68
Fax: +41 58 610 00 20

Contact Person: Frederike Brühschwein-Mandic, Senior Manager Regulatory Affairs

Preparation Date: March 20, 2018

Establishment Registration Number: 3001421318

II. Device:

Trade Name:	HAMILTON-C1, HAMILTON-T1 Collectively referred to as the HAMILTON-C1/T1 ventilators
Classification Name:	Ventilator, Continuous
Regulation:	21 CFR 868.5895
Product Code:	CBK (secondary: DQA)
Device Classification:	2

III. PREDICATE DEVICES:

HAMILTON-C1/T1 (K140939) (Predicate Device)

IV. REFERENCE DEVICE

HAMILTON-C3 (K161450)
Nihon Kohden NKV-550 Series Ventilator System (K181695)
Esprit Ventilator Speaking mode Option (K071212)

V. DEVICE DESCRIPTION:

The HAMILTON-C1 and HAMILTON-T1 ventilators are designed for adults, pediatrics, infants and neonatal patients requiring invasive or non-invasive ventilation support. All ventilators cover a range of clinical requirements, including invasive ventilation, automated ventilation with Adaptive Support Ventilation (ASV), and Non-Invasive Ventilation.

The previously cleared ventilators, HAMILTON-C1 and HAMILTON-T1 (both K140939), have been bundled together in this 510(k) submission in order to add the following new features:

- A modification to the software allows compatibility with the Nihon Kohden SpO2 sensors to be used with HAMIILTON-C1 and HAMILTON-T1 ventilators. These ventilators are already compatible and cleared for use with Masimo SpO2 sensors (K140939).
- cFlow was added, which continuously delivers an air/gas mixture.
- A modification to the software, which allows HAMILTON-C1/T1 ventilators to be compatible for use with speaking valves. A speaking valve allows tracheostomized adult and pediatric patients to communicate verbally.

VI. INDICATIONS FOR USE

The HAMILTON-C1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.

Intended areas of use:

- In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room
- During transfer of ventilated patients within the hospital

The HAMILTON-C1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

The HAMILTON-T1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.

Intended areas of use:

- In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room
- For emergency medical care
- During transport within and outside the hospital
- During transfer by rescue vehicles, fixed wing aircraft, helicopter or ship

The HAMILTON-T1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.

VII. SUMMARY OF THE TECHNOLOGY AND PERFORMANCE SPECIFICATIONS COMPARISON WITH THE PREDICATED DEVICES

Table 1: Comparison of the HAMILTON-C1/T1 with the predicate devices

Parameter	HAMILTON-C1/T1 (Proposed device)	HAMILTON-C1/T1 (Predicate device)	Comparison
Indications of Use	**HAMILTON-C1:** The HAMILTON-C1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.	**HAMILTON-C1:** The HAMILTON-C1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.	**HAMILTON-C1 and HAMILTON-T1:** Equivalent

Parameter	HAMILTON-C1/T1 (Proposed device)	HAMILTON-C1/T1 (Predicate device)	Comparison
	Intended areas of use: • In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital, or in the recovery room • During transfer of ventilated patients within the hospital The HAMILTON-C1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications. **HAMILTON-T1:** The HAMILTON-T1 ventilator is intended to provide positive pressure ventilatory support to adults, pediatrics, and optionally infants and neonates. Intended areas of use: • In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room • For emergency medical care • During transport within and outside the hospital • During transfer by rescue vehicles, fixed wing aircraft, helicopter or ship The HAMILTON-T1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.	Intended areas of use: • In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital, or in the recovery room • During transfer of ventilated patients within the hospital The HAMILTON-C1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications. **HAMILTON-T1:** The HAMILTON-T1 ventilator is intended to provide positive pressure ventilatory support to adults, pediatrics, and optionally infants and neonates. Intended areas of use: • In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room • For emergency medical care • During transport within and outside the hospital • During transfer by rescue vehicles, fixed wing aircraft, helicopter or ship The HAMILTON-T1 ventilator is a medical device intended for use by qualified, trained personnel under the direction of a physician and within the limits of its stated technical specifications.	
Control settings (Ranges) Adult/Ped	**HAMILTON-C1 and HAMILTON-T1:** • Apnea backup (On, automatic, off) • ETS (5 to 80%) • **Flow (2-60l/min)** • Flow trigger (0.1 to 20 l/min, off)	**HAMILTON-C1 and HAMILTON-T1:** • Apnea backup (On, automatic, off) • ETS (5 to 80%) • Flow trigger (0.1 to 20 l/min, off) • Gender (Male, female) • Loudness, alarm signals (1 to 10) • %MinVol (25 to 350%) • O2 monitoring (On, off)	**HAMILTON-C1 and HAMILTON-T1:** Substantially Equivalent

Parameter	HAMILTON-C1/T1 (Proposed device)	HAMILTON-C1/T1 (Predicate device)	Comparison
	• Gender (Male, female) • Loudness, alarm signals (1 to 10) • %MinVol (25 to 350%) • O2 monitoring (On, off) • CO2 monitoring (On, off) • SpO2 monitoring (On, off) • Oxygen (21 to 100%) • Pasvlimit (5 to 60 cm) • Patient height (30 to 250 cm) • Pcontrol (5 to 60 cmH2O) • PEEP/CPAP (0 to 35 cmH2O) • Pinsp (5 to 60 cmH2O) • P-ramp (0 to 2000 ms) • Psupport (0 to 60 cmH2O) • Phigh (0 to 60 cmH2O) • Plow (0 to 35 cmH2O) • Rate (1 to 80 b/min) • Sigh (On, off) • Thigh (0.1 to 40 s) • TI (0.1 to 12 s) • TImax (1 to 3 s) • Tlow (0.2 to 40 s) • Vt (20 to 2000 ml)	• CO2 monitoring (On, off) • SpO2 monitoring (On, off) • Oxygen (21 to 100%) • Pasvlimit (5 to 60 cm) • Patient height (30 to 250 cm) • Pcontrol (5 to 60 cmH2O) • PEEP/CPAP (0 to 35 cmH2O) • Pinsp (5 to 60 cmH2O) • P-ramp (0 to 2000 ms) • Psupport (0 to 60 cmH2O) • Phigh (0 to 60 cmH2O) • Plow (0 to 35 cmH2O) • Rate (1 to 80 b/min) • Sigh (On, off) • Thigh (0.1 to 40 s) • TI (0.1 to 12 s) • TImax (1 to 3 s) • Tlow (0.2 to 40 s) • Vt (20 to 2000 ml)	
Control settings (Ranges) NEO	**HAMILTON-C1 and HAMILTON-T1:** • Apnea backup (On, automatic, off) • ETS (5 to 80%) • **Flow (2-12 l/min)** • Flow trigger (0.1 to 20 l/min, off) • Loudness, alarm signals (1 to 10) • O2 monitoring (On, off) • CO2 monitoring (On, off) • SpO2 monitoring (On, off) • Oxygen (21 to 100%) • Pcontrol (0 to 45 cmH2O) • PEEP/CPAP (3 to 25 cmH2O) • Pinsp (3 to 45 cmH2O) • P-ramp (0 to 600 ms) • Psupport (0 to 45 cmH2O) • Phigh (0 to 45 cmH2O) • Plow (0 to 25 cmH2O) • Rate (1 to 80 b/min) • Thigh (0.1 to 40 s) • TI (0.1 to 12 s) • TImax (1 to 3 s) • Tlow (0.25 to 40 s) • Vt (2 to 300 ml)	**HAMILTON-C1 and HAMILTON-T1:** • Apnea backup (On, automatic, off) • ETS (5 to 80%) • Flow trigger (0.1 to 20 l/min, off) • Loudness, alarm signals (1 to 10) • O2 monitoring (On, off) • CO2 monitoring (On, off) • SpO2 monitoring (On, off) • Oxygen (21 to 100%) • Pcontrol (0 to 45 cmH2O) • PEEP/CPAP (3 to 25 cmH2O) • Pinsp (3 to 45 cmH2O) • P-ramp (0 to 600 ms) • Psupport (0 to 45 cmH2O) • Phigh (0 to 45 cmH2O) • Plow (0 to 25 cmH2O) • Rate (1 to 80 b/min) • Thigh (0.1 to 40 s) • TI (0.1 to 12 s) • TImax (1 to 3 s) • Tlow (0.25 to 40 s) • Vt (2 to 300 ml) • Weight (0.2 kg to 30 kg)	**HAMILTON-C1 and HAMILTON-T1:** Substantially Equivalent

Parameter	HAMILTON-C1/T1 (Proposed device)	HAMILTON-C1/T1 (Predicate device)	Comparison
	• Weight (0.2 kg to 30 kg)		
Control settings (Default settings) Adult/Ped	**HAMILTON-C1 and HAMILTON-T1:** • Apnea backup (On) • ETS (25%) • **Flow (15 l/min)** • Flow trigger (5 l/min) • Gender (Male) • Loudness, alarm signals (5) • %MinVol (100%) • O_2 monitoring (On) • CO_2 monitoring (Off) • SpO2 monitoring (Off) • Oxygen (50%) • Pasvlimit (30 cm) • Patient height (174 cm) • Pcontrol (15 cmH2O) • PEEP/CPAP (5 cmH2O) • Pinsp (15 cmH2O) • P-ramp (50 ms) • Psupport (15 cmH2O) • Phigh (20 cmH2O) • Plow (5 cmH2O) • Rate (10 b/min) • Sigh (Off) • Thigh (2.0 s) • TI (1 s) • TImax (1.5 s) • Tlow (4.0 s) • Vt (700 ml)	**HAMILTON-C1 and HAMILTON-T1:** • Apnea backup (On) • ETS (25%) • Flow trigger (5 l/min) • Gender (Male) • Loudness, alarm signals (5) • %MinVol (100%) • O_2 monitoring (On) • CO_2 monitoring (Off) • SpO2 monitoring (Off) • Oxygen (50%) • Pasvlimit (30 cm) • Patient height (174 cm) • Pcontrol (15 cmH2O) • PEEP/CPAP (5 cmH2O) • Pinsp (15 cmH2O) • P-ramp (50 ms) • Psupport (15 cmH2O) • Phigh (20 cmH2O) • Plow (5 cmH2O) • Rate (10 b/min) • Sigh (Off) • Thigh (2.0 s) • TI (1 s) • TImax (1.5 s) • Tlow (4.0 s) • Vt (700 ml)	**HAMILTON-C1 and HAMILTON-T1:** Substantially Equivalent
Control settings (Default settings) Neo	**HAMILTON-C1 and HAMILTON-T1:** • Apnea backup (On) • ETS (25%) • **Flow (2 l/min)** • Flow trigger (0.5 l/min) • Loudness, alarm signals (3) • O_2 monitoring (On) • CO_2 monitoring (Off) • SpO2 monitoring (Off) • Oxygen (40%) • Pcontrol (15 cmH2O) • PEEP/CPAP (5 cmH2O)	**HAMILTON-C1 and HAMILTON-T1:** • Apnea backup (On) • ETS (25%) • Flow trigger (0.5 l/min) • Loudness, alarm signals (3) • O_2 monitoring (On) • CO_2 monitoring (Off) • SpO2 monitoring (Off) • Oxygen (40%) • Pcontrol (15 cmH2O) • PEEP/CPAP (5 cmH2O) • Pinsp (15 cmH2O) • P-ramp (50 ms)	**HAMILTON-C1 and HAMILTON-T1:** Substantially Equivalent

Parameter	HAMILTON-C1/T1 (Proposed device)	HAMILTON-C1/T1 (Predicate device)	Comparison
	• Pinsp (15 cmH2O) • P-ramp (50 ms) • Psupport (15 cmH2O) • Phigh (20 cmH2O) • Plow (5 cmH2O) • Rate (derived from the body weight setting b/min) • Thigh (based on rate s) • TI (1 s) • TImax (based on weight s) • Tlow (based on weight s) • Vt (based on weight ml) • Weight (2.0 kg)	• Psupport (15 cmH2O) • Phigh (20 cmH2O) • Plow (5 cmH2O) • Rate (derived from the body weight setting b/min) • Thigh (based on rate s) • TI (1 s) • TImax (based on weight s) • Tlow (based on weight s) • Vt (based on weight ml) • Weight (2.0 kg)	
Modes of ventilation	**HAMILTON-C1 and HAMILTON-T1:** • ASV • (S)CMV+ • SIMV+ • PCV+ • PSIMV+ • SPONT • DuoPAP • APRV • NIV • NIV-ST • nCPAP • nCPAP-PC •	**HAMILTON-C1 and HAMILTON-T1:** • ASV • (S)CMV+ • SIMV+ • PCV+ • PSIMV+ • SPONT • DuoPAP • APRV • NIV • NIV-ST • nCPAP • nCPAP-PC	**HAMILTON-C1 and HAMILTON-T1:** Equivalent
Alarms, non-adjustable (Priorities)	**HAMILTON-C1 and HAMILTON-T1:** • Air supply (high) • Apnea (high) • Apnea ventilation (low) • Apnea ventilation ended (low) • ASV: Cannot meet the target (low) • Battery power loss (high) • Battery low (high) • Battery 1/2 wrong (low) • Battery 1/2 calibration required (low) • Battery 1/2 temperature high (high) • Blower service required (low) • Check Flow Sensor (high) • Check Flow Sensor tubing (high) • **Check for blockage (high)** • Device temperature high (high) • Disconnection (high) • Disconnection on patient side (high)	**HAMILTON-C1 and HAMILTON-T1:** • Air supply (high) • Apnea (high) • Apnea ventilation (low) • Apnea ventilation ended (low) • ASV: Cannot meet the target (low) • Battery power loss (high) • Battery low (high) • Battery 1/2 wrong (low) • Battery 1/2 calibration required (low) • Battery 1/2 temperature high (high) • Blower service required (low) • Check Flow Sensor (high) • Check Flow Sensor tubing (high) • Device temperature high (high) • Disconnection (high) • Disconnection on patient side (high) • Disconnection on ventilator side (high) • Exhalation obstructed (high) • Exhalation port occluded (high) • External flow sensor failed (high)	**HAMILTON-C1 and HAMILTON-T1:** Substantially Equivalent

Parameter	HAMILTON-C1/T1 (Proposed device)	HAMILTON-C1/T1 (Predicate device)	Comparison
	• Disconnection on ventilator side (high) • Exhalation obstructed (high) • Exhalation port occluded (high) • External flow sensor failed (high) • Fan failure (medium) • Flow (high, low after silencing) • Flow sensor calibration needed (High) • High pressure during sigh (high) • High tidal volume (medium) • IRV (low) • Loss of external power (low) • Loss of PEEP (medium) • Obstruction (high) (only for nCPAP and nCPAP-PC modes) • O2 sensor calibration needed (low) • O2 sensor defective (low) • O2 sensor missing (low) • O2 sensor not system-compatible (low) • Oxygen supply failed (high) • SpO2 adapter missing (medium) • SpO2 sensor error (medium) • SpO2 light interference (medium) • SpO2 low perfusion index (medium) • SpO2 Patient disconnected (medium) • SpO2 Probe missing (medium) • Performance limited by high altitude (medium)	• Fan failure (medium) • Flow (high, low after silencing) • Flow sensor calibration needed (High) • High pressure during sigh (high) • High tidal volume (medium) • IRV (low) • Loss of external power (low) • Loss of PEEP (medium) • Obstruction (high) (only for nCPAP and nCPAP-PC modes) • O2 sensor calibration needed (low) • O2 sensor defective (low) • O2 sensor missing (low) • O2 sensor not system-compatible (low) • Oxygen supply failed (high) • SpO2 adapter missing (medium) • SpO2 sensor error (medium) • SpO2 light interference (medium) • SpO2 low perfusion index (medium) • SpO2 Patient disconnected (medium) • SpO2 Probe missing (medium) • Performance limited by high altitude (medium)	
Alarm settings (Ranges), Adult	**HAMILTON-C1 and HAMILTON-T1:** • Apnea time (15 to 60 s) • ExpMinVol low (Off, 0.1 to 50 l/min) • ExpMinVol high (0.1 to 50, Off l/min) • fTotal low (0 to 99 b/min) • fTotal high (0 to 99 b/min) • Oxygen low (18 to 97%) • Oxygen high (18 to 105%) • PetCO2 low (Off, 0 to 100 mmHg) • PetCO2 high (Off, 1 to 100 mmHg)	**HAMILTON-C1 and HAMILTON-T1:** • Apnea time (15 to 60 s) • ExpMinVol low (Off, 0.1 to 50 l/min) • ExpMinVol high (0.1 to 50, Off l/min) • fTotal low (0 to 99 b/min) • fTotal high (0 to 99 b/min) • Oxygen low (18 to 97%) • Oxygen high (18 to 105%) • PetCO2 low (Off, 0 to 100 mmHg) • PetCO2 high (1 to 100 mmHg) • Pressure high (15 to 70 cmH2O) • Pressure low (4 to 60 cmH2O) • Pressure limitation (5 to 60 cmH2O)	**HAMILTON-C1 and HAMILTON-T1:** Equivalent

Parameter	HAMILTON-C1/T1 (Proposed device)	HAMILTON-C1/T1 (Predicate device)	Comparison
	• Pressure high (15 to 70 cmH2O) • Pressure low (4 to 60 cmH2O) • Pressure limitation (5 to 60 cmH2O) • Vt low (10 to 3000, Off ml) • Vt high (Off, 10 to 3000 ml) • SpO2 high (71 to 100, Off %) • SpO2 low (70 to 99, Off %) • Pulse high (35 to 235 1/min) • Pulse low (30 to 230 1/min) • PI high (0.04 to 19, Off %) • PI low (Off/0.03 to 18 %) • PVI high (2 to 100, Off) • PVI low (Off, 1 to 99)	• Vt low (10 to 3000, Off ml) • Vt high (Off, 10 to 3000 ml) • SpO2 high (71 to 100, Off %) • SpO2 low (70 to 99, Off %) • Pulse high (35 to 235 1/min) • Pulse low (30 to 230 1/min) • PI high (0.04 to 19, Off %) • PI low (Off/0.03 to 18 %) • PVI high (2 to 100, Off) PVI low (Off, 1 to 99)	
Alarm settings (Ranges), Neonatal	• Apnea time (5 to 60 s) • ExpMinVol low (Off, 0.01 to 10, Off l/min) • ExpMinVol high (0.03 to 10 l/min, Off) • Flow (8 to 30 l/min) • fTotal low (0 to 200 b/min) • fTotal high (2 to 210 b/min) • Oxygen low (18 to 97%) • Oxygen high (18 to 105%) • PetCO2 low (Off, 0 to 100 mmHg) • PetCO2 high (1 to 100 mmHg) • Pressure high (10 to 55 cmH2O) • Pressure low (2 to 55 cmH2O) • Pressure limitation (5 to 60 cmH2O) • Vt low (Off, 0.1 to 300 ml) • Vt high (0.1 to 300, Off ml) • SpO2 high (71 to 100, Off %) • SpO2 low (70 to 99, Off %) • Pulse high (35 to 235 1/min) • Pulse low (30 to 230 1/min) • PI high (0.04 to 19, Off %) • PI low (Off/0.03 to 18 %) • PVI high (2 to 100, Off) • PVI low (Off, 1 to 99)	• Apnea time (5 to 60, Off s) • ExpMinVol low (Off, 0.01 to 10 l/min) • ExpMinVol high (0.03 to 10 l/min, Off) • Flow (8 to 30 l/min) • fTotal low (0 to 200 b/min) • fTotal high (2 to 210 b/min) • Oxygen low (18 to 97%) • Oxygen high (18 to 105%) • PetCO2 low (Off, 0 to 100 mmHg) • PetCO2 high (1 to 100 mmHg) • Pressure high (10 to 55 cmH2O) • Pressure low (2 to 55 cmH2O) • Pressure limitation (5 to 60 cmH2O) • Vt low (Off, 0.1 to 300 ml) • Vt high (0.1 to 300, Off ml) • SpO2 high (71 to 100, Off %) • SpO2 low (70 to 99, Off %) • Pulse high (35 to 235 1/min) • Pulse low (30 to 230 1/min) • PI high (0.04 to 19, Off %) • PI low (Off/0.03 to 18 %) • PVI high (2 to 100, Off) • PVI low (Off, 1 to 99)	**HAMILTON-C1 and HAMILTON-T1:** Equivalent

Hamilton Medical has demonstrated the modified HAMILTON-C1 and HAMILTON-T1 ventilators to be substantially equivalent to currently marketed predicate devices, which have been previously cleared by FDA.

VIII. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE REFERENCE DEVICES

The Nihon Kohden NKV-550 Series Ventilator System is used as a reference device for the proposed HAMILTON-C1/T1 as both the reference device and the proposed device are intensive care ventilators which have the O2 therapy/cFlow feature.

The HAMILTON-C3 is used as a reference device for the proposed HAMILTON-C1/T1 as both the reference device and the proposed device are intensive care ventilators which can be used with Nihon Kohden SpO2 sensors and accessories.

The Esprit Ventilator V200 with Speaking mode Option is used as a reference device for the proposed Speaking valve compatibility on the modified HAMILTON-C1/T1, which is only available in invasive modes for tracheostomized patients with the use of a special speaking valve, for example the Passy-Muir valve.

IX. NON-CLINICAL PERFORMANCE TESTS

The following performance and nonclinical data are provided in support of the substantial equivalence determination.

The Software Design and Validation process, together with the bench testing of the device, demonstrated that the HAMILTON-C1/T1 operates as intended.

In particular, testing demonstrated that the HAMILTON-C1/T1 is compliant with the following guidelines and standards:

- ANSI/AAMI ES60601-1 (2005/ (R) 2012): Medical electrical equipment – General Requirements for Safety
- IEC 60601-1-2 (2014): Medical electrical equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- ISO 80601-2-12 (2011): Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
- IEC 60601-1-8 (2006 + Am.1: 2012): Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60601-1-6 (2010 + A1 :2013): Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 62366 (2014): Medical devices - Application of usability engineering to medical de- vices
- ANSI/AAMI HE75(2009(R) 2013): Human factors engineering – Design of medical de- vices
- IEC 62304 (2006): Medical device software - Software life-cycle processes
- ISO 80601-2-55 (2011): Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-61 (2011): Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

- AIM 7351731: Medical Electrical Equipment and System Electromagnetic Immunity Test for Exosure to Radio Frequency Identification Readers

Additional software verification and validation testing were completed as recommended by the FDA's "Guidance for Industry and FDA Staff: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Testing of the modified HAMILTON-C1/T1, with the new features, was conducted. The new features cFlow, Speaking Valve, and the use of Nihon Kohden SpO2 sensors were subjected to comparison testing with legally marketed devices. Furthermore, waveform comparison testing was completed for the Speaking Valve Feature. The data provided from these tests was shown to be equivalent to the legally marketed devices.

Since only materials already used in in the predicate (cleared under document number K140939) are described with this 510(k), Hamilton Medical did not conduct any additional biocompatibility testing.

X. CONCLUSION

The results of verification, validation, and testing activities demonstrate that the modified HAMILTON-C1 and HAMILTON-T1 ventilators are substantially equivalent to the legally marketed devices identified herein.