May 4, 2020

Hamilton Medical AG
Simone Haller
Regulatory Affairs Specialist
Via Crush 8
Bonaduz, 7402 Ch

Re: K193228
Trade/Device Name: Hamilton-G5
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK, DQA
Dated: April 1, 2020
Received: April 3, 2020

Dear Simone Haller:

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 J. 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193228

Device Name

HAMILTON-G5

Indications for Use *(Describe)*

The HAMILTON-G5 ventilator is designed for intensive care ventilation of adult and pediatric patients, and optionally infant and neonatal patients. The device is intended for use in the hospital and institutional environment where health care professionals provide patient care. The HAMILTON-G5 ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician.

The HAMILTON-G5 ventilator may be used for transport within a hospital or hospital type facility provided compressed gas is supplied. The device is not to be used in the presence of flammable anesthetic agents or other ignition sources. The ventilator is not to be used in an environment with magnetic resonance imaging (MRI) equipment. The device is not intended for transportation outside the hospital or for use in the home environment.

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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HAMILTON MEDICAL
Intelligent Ventilation since 1983

HAMILTON-G5

510(k) SUMMARY

I. SUBMITTER

Hamilton Medical AG
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Contact Person: Simone Haller, Regulatory Affairs Specialist

Date Prepared: 2019-11-18

II. DEVICE

Name of Devices: HAMILTON-G5
Common or Usual Name: Continuous ventilator
Regulation Number and Name: Ventilator, Continuous (21 CFR 868.5895)
Device Classification: 2
Product Code: CBK (secondary: DQA)

III. PREDICATE DEVICE

HAMILTON-G5 (K180295) (primary predicate device)

IV. REFERENCE DEVICES

Hamilton Medical AG: HAMILTON-H900 (K152029, K163283)
RESPIRONICS CALIFORNIA, INC: V200 VENTILATOR (K102054)

V. DEVICE DESCRIPTION

The HAMILTON-G5 ventilator is designed for adults, pediatrics, infants and neonates requiring invasive or non-invasive ventilation support. It covers a range of clinical modes, including invasive ventilation, Adaptive Support Ventilation (ASV), and noninvasive ventilation.
The 510(k) submission intends to add the following new features to the previously cleared ventilator HAMILTON-G5:

- IntelliSync+, an option that allows the device to dynamically update the inspiratory or cycling trigger
- Operation of the humidifier HAMILTON-H900 via the GUI of the ventilator HAMILTON-G5

VI. INDICATIONS FOR USE

The HAMILTON-G5 ventilator is designed for intensive care ventilation of adult and pediatric patients, and optionally infant and neonatal patients. The device is intended for use in the hospital and institutional environment where health care professionals provide patient care. The HAMILTON-G5 ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician. The HAMILTON-G5 ventilator may be used for transport within a hospital or hospital type facility provided compressed gas is supplied. The device is not to be used in the presence of flammable anesthetic agents or other ignition sources. The ventilator is not to be used in an environment with magnetic resonance imaging (MRI) equipment. The device is not intended for transportation outside the hospital or for use in the home environment.

VII. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE AND REFERENCE DEVICES

A comparative summary of the technological characteristics of the HAMILTON-G5 with the primary predicate, the predicate and the reference device is presented in the tables below.

Table 1: Comparison of HAMILTON-G5 with the primary predicate device

Parameters	Subject device: HAMILTON-G5	Primary predicate device: Currently marketed HAMILTON-G5	Comparison
Indication for Use	The HAMILTON-G5 ventilator is designed for intensive care ventilation of adult and pediatric patients, and optionally infant and neonatal patients. The device is intended for use in the hospital and institutional environment where health care professionals provide patient care. The HAMILTON-G5 ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician. The HAMILTON-G5 ventilator may be used for transport within a hospital or hospital type facility provided compressed gas is supplied. The device is not to be used in the presence of flammable anesthetic agents or other ignition sources. The ventilator is not to be used in an environment with magnetic resonance imaging (MRI) equipment. The device is not intended for transportation outside the hospital or for use in the home environment.	The HAMILTON-G5 ventilator is designed for intensive care ventilation of adult and pediatric patients, and optionally infant and neonatal patients. The device is intended for use in the hospital and institutional environment where health care professionals provide patient care. The HAMILTON-G5 ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician. The HAMILTON-G5 ventilator may be used for transport within a hospital or hospital type facility provided compressed gas is supplied. The device is not to be used in the presence of flammable anesthetic agents or other ignition sources. The ventilator is not to be used in an environment with magnetic resonance imaging (MRI) equipment. The device is not intended for transport outside the hospital or for use in the home environment.	Same
Environment of Use	Hospitals, hospital-type facilities and in-hospital transportation for patients who need ventilation therapy	Hospitals, hospital-type facilities and in-hospital transportation for patients who need ventilation therapy	Same
Anatomical Site	Patient airways	Patient airways	Same
Target Population	Adult, pediatric, infant and neonatal patients	Adult, pediatric, infant and neonatal patients	Same
Performance	Met ISO 80601-2-12 requirements on essential performance of critical care ventilator.	Met ISO 80601-2-12 requirements on essential performance of critical care ventilator.	Same
Chemicals delivered to patient	Medical Air and Oxygen (optional Heliox)	Medical Air and Oxygen (optional Heliox)	Same

Parameters	Subject device: HAMILTON-G5	Primary predicate device: Currently marketed HAMILTON-G5	Comparison
Energy used for device	AC and battery	AC and battery	Same
New feature; Settings (Ranges)	• HAMILTON-H900 settings: - Temperature (HAMILTON-H900 ET 35 to 41 °C / NIV 30 to 35 °C) - Humidity (-2 to 3 °C) - Standby On (HAMILTON-H900 On/Off) - Power On/Off (HAMILTON-H900 On/Off) - Auto Mode (HAMILTON-H900 On/Off) - NIV (HAMILTON-H900 On/Off) - Expiratory Lim Temperature Increase (HAMILTON-H900 On/Off) • Alarm Silence (HAMILTON-H900 On/Off)		Added functionality based on HAMILTON-H900 reference
Modes of ventilation	• ASV • APVcmv • APVsimv • P-CMV • P-SIMV • SPONT • DuoPAP • APRV • (S)CMV • SIMV • VS • nCPAP-PS • NIV • NIV-ST	• ASV • APVcmv • APVsimv • P-CMV • P-SIMV • SPONT • DuoPAP • APRV • (S)CMV • SIMV • VS • nCPAP-PS • NIV • NIV-ST	Same
Therapy types	Invasive, non-invasive, Hi Flow O2 (High flow)	Invasive, non-invasive, Hi Flow O2 (High flow)	Same
Trigger	Pressure trigger, flow trigger, trigger off	Pressure trigger, flow trigger, trigger off	Same
New feature; Trigger	IntelliSync+		Please refer to Table 2

Parameters	Subject device: HAMILTON-G5	Primary predicate device: Currently marketed HAMILTON-G5	Comparison
Alarms, non-adjustable	• Oxygen alarm limit exceeded • Oxygen concentration • Disconnection • Loss of PEEP • Exhalation obstruction • High PEEP • ASV/APV • CO2 • Power supply • Gas supply • Cuff leakage • Nebulizer disconnected • Cannot reach target flow • Cuff disconnection • Check for blockage	• Oxygen alarm limit exceeded • Oxygen concentration • Disconnection • Loss of PEEP • Exhalation obstruction • High PEEP • ASV/APV • CO2 • Power supply • Gas supply • Cuff leakage • Nebulizer disconnected • Cannot reach target flow • Cuff disconnection • Check for blockage	Same
New feature; Alarms, non-adjustable	• Following humidifier alarms are transmitted from the humidifier HAMILTON-H900 to the HAMILTON-G5: - Humidifier tilt - Humidifier chamber temp high / Humidifier y-piece temp high - Humidifier water high - Humidifier chamber temp low / Humidifier y-piece temp low - Humidifier water low - Humidifier check chamber - Humidifier check left tube / Humidifier check right tube - Humidifier error - Check humidifier - Check communication interface humidifier		Added functionality based on HAMILTON-H900 reference
Alarms, adjustable	• Low/high minute volume • Low/high pressure	• Low/high minute volume • Low/high pressure	Same

Parameters	Subject device: HAMILTON-G5	Primary predicate device: Currently marketed HAMILTON-G5	Comparison
	• Low/high tidal volume • Low/high respiratory rate • Apnea time • Low/high PetCO2 • Low/high pulse • Low/high SpO2 • Low/high SpMet • Low/high SpOC • %leak • PI (perfusion index)	• Low/high tidal volume • Low/high respiratory rate • Apnea time • Low/high PetCO2 • Low/high pulse • Low/high SpO2 • Low/high SpMet • Low/high SpOC • %leak • PI (perfusion index)	

As can be seen in Table 1 above, the subject device HAMILTON-G5 has the same technological characteristics as the primary predicate HAMILTON-G5. Thus, the comparison of the HAMILTON-G5 to its primary predicate device does not raise new safety and effectiveness concerns.

Table 2: Comparison of HAMILTON-G5 with the reference predicate device

Parameters	Subject device: HAMILTON-G5	Reference predicate device: Respironics V200 Ventilator	Comparison
Indication for Use	The HAMILTON-G5 ventilator is designed for intensive care ventilation of adult and pediatric patients, and optionally infant and neonatal patients. The device is intended for use in the hospital and institutional environment where health care professionals provide patient care. The HAMILTON-G5 ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician. The HAMILTON-G5 ventilator may be used for transport within a hospital or hospital type facility provided compressed gas is supplied. The device is not to be used in the presence of flammable anesthetic agents or other ignition sources. The ventilator is not to be used in an environment with magnetic resonance imaging (MRI) equipment. The device is not intended for transportation outside the hospital or for use in the home environment.	The Respironics V200 Ventilator is a microprocessor-controlled, electrically powered mechanical ventilator. It is intended for use by qualified medical personnel to provide continuous or intermittent ventilatory support for adult, pediatric, and neonatal patients as prescribed by a physician. The ventilator is intended for use in either invasive or non-invasive applications in institutional environments.	Substantially equivalent

Parameters	Subject device: HAMILTON-G5	Reference predicate device: Respironics V200 Ventilator	Comparison
Trigger	IntelliSync+: • Noninvasive method • Synchronization independent of ventilation mode • Automated setting of inspiratory trigger • Real-time setting of inspiratory trigger within the breath • Real-time setting of cycling within the breath • Trigger during negative flow possible	Auto-Trak: • Noninvasive method • Synchronization independent of ventilation mode • Automated setting of inspiratory trigger • Real-time setting of inspiratory trigger within the breath • Real-time setting of cycling within the breath • Trigger during negative flow possible	Same
Trigger performance	A bench and waveform testing report has been submitted.		Substantially equivalent

The subject device HAMILTON-G5 is compared to the predicate device Respironics V200 Ventilator regarding the trigger synchronization algorithm, which resulted in equivalence regarding the trigger features itself and in substantial equivalence regarding the trigger performance (Table 2).

VIII. PERFORMANCE DATA

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-G5 operates as intended.

In particular, testing demonstrated that the HAMILTON-G5 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 devices
- ANSI/AAMI HE75(2009(R) 2013): Human factors engineering – Design of medical devices
- 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

Additional software verification and validation testing was conducted and documentation was provided 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 to be 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 new feature IntelliSync+ with the HAMILTON-G5 was conducted by waveform performance testing. The data provided from this test was shown to be substantially equivalent to the legally marketed predicate device.

Since only materials already used in in the primary predicate (cleared under document number K180295) are used (the new features did not include any material changes, only software adaptions) Hamilton Medical did not conduct any additional biocompatibility testing.

IX. CONCLUSION

The results of verification, validation, and testing activities demonstrate that the modified HAMILTON-G5 ventilator is substantially equivalent to the legally marketed predicate devices identified herein.