July 30, 2019

Hamilton Medical AG
Annemarie Hoft
Quality Engineer
Via Crusch 8
Bonaduz, 7402 CH

Re: K180295
Trade/Device Name: Hamilton-G5
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK, DQA
Dated: May 28, 2019
Received: May 31, 2019

Dear Annemarie Hoft:

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
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)*

K180295

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 com-pressed 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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510(k) SUMMARY

I. SUBMITTER

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Contact Person: Frederike Brühschwein-Mandic, Senior Manager Regulatory Affairs
Date Prepared: 13th March 2019

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 (K131774)

IV. REFERENCE DEVICE

Nihon Kohden NKV-550 Series Ventilator System (K181695)

V. DEVICE DESCRIPTION

The HAMILTON-G5 is designed for adult, pediatric, infant, and neonatal patients requiring invasive or noninvasive 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:

- The following new feature for adult, pediatric, infant and neonatal patient group: cFlow

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 DEVICES

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

Technical Characteristic	Predicate device: HAMILTON-G5 (K131774)	Proposed device: HAMILTON-G5	Comparison
Indications of Use	The HAMILTON-G5 ventilator is designed for intensive care ventilation of adult and paediatric patients, and optionally infant and neonatal patients. The device is intended for use in the hospital and institu- tional 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 physi- cian. The HAMILTON-G5 ventilator may be used for transport within a hospital or hospital type facility provided com- pressed gas is supplied. The device is not to be used in the presence of flammable anaesthetic 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 paediatric 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 anaesthetic 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.	Same
Settings (Ranges)	• Ventilation modes (ASV,APVcmv,APVsimv,P-CMV,P-SIMV, SPONT, DuoPAP, APRV,(S)CMV, SIMV, VS, NIV, NIV-ST, nCPAP-PS) • Patient groups(Adult, Pediatric, Neonates (optional) • Patient height (30 to 250 cm) • Patient gender (male/female) • (S)CMV (5 to 120 b/min) • P-CMV (5 to 150 b/min)	• Ventilation modes (ASV,APVcmv,APVsimv,P-CMV,P-SIMV, SPONT, DuoPAP,APRV,(S)CMV, SIMV, VS, NIV, NIV-ST, nCPAP-PS) • Patient groups(Adult, Pediatric, Neonates (optional) • Patient height (30 to 250 cm) • Patient gender (male/female) • (S)CMV (5 to 120 b/min) • P-CMV (5 to 150 b/min)	Substantially Equivalent

Technical Characteristic	Predicate device: HAMILTON-G5 (K131774)	Proposed device: HAMILTON-G5	Comparison
	• SIMV (1 to 60 b/min) • P-SIMV (1 to 60 b/min) • APVcmv (5 to 150 b/min) • APVsimv (1 to 80 b/min) • DuoPAP (1 to 80 b/min) • APRV (5 to 150 b/min) • nCPAP-PS (15 to 150 b/min) • Tidal volume (2 to 2000 ml) • PEEP/CPAP (Plow) (0 to 50 cmH2O) • Oxygen (21% to 100%) • I:E ratio (1:9 to 4:1) • I:E ratio APRV/DuoPAP(1:599 to 149:1) • Inspiratory time (0.1 to 10s) • Inspiratory time spont (0.25 to 3 s) • % Inspiratory time (10% to 80% of cycle time, max 10s) • Inspiratory pause time (0 to 8 s) • Pause time (0 to 8 s, 0% to 70% of cycle time) • Peak flow (1 to 180l/min) • T low APRV (0.1 to 30s) • T high DuoPAP/APRV (0.1 to 30s) • Pressure trigger below PEEP/CPAP (off, 0.1 to 10 cmH2O) • Flow trigger (0.5 to 15 l/min) • Automatic base flow (1 to 30 l/min) • Pressure control (3 to 100 cmH2O) • Pressure support (3 to 100 cmH2O) • P high DuoPAP/APRV (0 to 50 cmH2O) • Pressure ramp (50 to 200 ms (P-CMV and APRV) 25 - 200 other modes) • Cuff pressure (0 to 50 cm H2O) • % minute volume (25% to 350%) • Flow patterns (Sine, square, dec., 50% dec.) • Expiratory trigger sensitivity (5% to 70% of inspiratory peak flow) • Alarm silence (On/OFF) • Alarm loudness (51 dB to 73 dB)	• SIMV (1 to 60 b/min) • P-SIMV (1 to 60 b/min) • APVcmv (5 to 150 b/min) • APVsimv (1 to 80 b/min) • DuoPAP (1 to 80 b/min) • APRV (5 to 150 b/min) • nCPAP-PS (15 to 150 b/min) • **cFlow (Flow 1-60 l/min)** • Tidal volume (2 to 2000 ml) • PEEP/CPAP (Plow) (0 to 50 cmH2O) • Oxygen (21% to 100%) • I:E ratio (1:9 to 4:1) • I:E ratio APRV/DuoPAP(1:599 to 149:1) • Inspiratory time (0.1 to 10s) • Inspiratory time spont (0.25 to 3 s) • % Inspiratory time (10% to 80% of cycle time, max 10s) • Inspiratory pause time (0 to 8 s) • Pause time (0 to 8 s, 0% to 70% of cycle time) • Peak flow (1 to 180l/min) • T low APRV (0.1 to 30s) • T high DuoPAP/APRV (0.1 to 30s) • Pressure trigger below PEEP/CPAP (off, 0.1 to 10 cmH2O) • Flow trigger (0.5 to 15 l/min) • Automatic base flow (1 to 30 l/min) • Pressure control (3 to 100 cmH2O) • Pressure support (3 to 100 cmH2O) • P high DuoPAP/APRV (0 to 50 cmH2O) • Pressure ramp (50 to 200 ms (P-CMV and APRV) 25 - 200 other modes) • Cuff pressure (0 to 50 cm H2O) • % minute volume (25% to 350%) • Flow patterns (Sine, square, dec., 50% dec.) • Expiratory trigger sensitivity (5% to 70% of inspiratory peak flow) • Alarm silence (On/OFF) • Alarm loudness (51 dB to 73 dB)	
Modes of ventilation	• ASV • APVcmv • APVsimv • P-CMV • P-SIMV	• ASV • APVcmv • APVsimv • P-CMV • P-SIMV	Same

Technical Characteristic	Predicate device: HAMILTON-G5 (K131774)	Proposed device: HAMILTON-G5	Comparison
	• SPONT • DuoPAP • APRV • (S)CMV • SIMV • VS • nCPAP-PS • NIV • NIV-ST	• SPONT • DuoPAP • APRV • (S)CMV • SIMV • VS • nCPAP-PS • NIV • NIV-ST	
Alarms, non-adjustable	• Oxygen alarm limit exceeded • Oxygen concentration • Disconnection • Loss of PEEP • Exhalation obstruction • High PEEP • ASV/APV • CO2 • Power supply • Gas supplies • Cuff leakage • Nebulizer disconnected • Cannot reach target flow • Cuff Disconnection	• Oxygen alarm limit exceeded • Oxygen concentration • Disconnection • Loss of PEEP • Exhalation obstruction • High PEEP • ASV/APV • CO2 • Power supply • Gas supplies • Cuff leakage • Nebulizer disconnected • Cannot reach target flow • Cuff Disconnection • **Check for blockage**	Substantially Equivalent
Alarms, adjustable	• Low/high minute volume • Low/high pressure • 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 minute volume • Low/high pressure • 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)	Same

Hamilton Medical has demonstrated the modified HAMILTON-G5 ventilator to be substantial equivalent to the currently marketed predicate device HAMILTON-G5 (K131744) that has been previously cleared by FDA.

VIII. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE REFERENCE DEVICES

Table 2: Comparison of the HAMILTON-G5 with Reference device (Nihon Kohden NKV-550 Series Ventilator System.

The Nihon Kohden NKV-550 Series Ventilator System is used as a reference device for the proposed HAMILTON-G5 as both the reference device and the proposed device are intensive care ventilators which have the O2 therapy/cFlow feature.

Technical Characteristic	Reference Device: Nihon Kohden NKV-550 Series Ventilator System (K181695)	Proposed Device: HAMILTON-G5	Comparison
Indication for Use	The Nihon Kohden NKV-550 Series Ventilator System is intended to provide continuous ventilation for adult, pediatric and neonatal patients who require invasive or noninvasive respiratory support. The NKV-550 offers mandatory and spontaneous ventilation modes as well as Respiratory monitoring. The NKV-550 is intended for use in hospitals and hospital-type facilities, as well as for in-hospital transportation	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	Substantially Equivalent
Environment of Use	Hospitals, hospital-type facilities and in-hospital transportation for patients who need ventilation therapy	The device is intended for use in the hospital and institutional environment where healthcare professionals provide patient care	Substantially Equivalent
Anatomical Site	Patient airways	Patient airways	Same
Target Population	Adult, pediatric and neonatal patients	Adult, pediatric, infant and neonatal patients	Same Further defined pediatric to include infant

Technical Characteristic	Reference Device: Nihon Kohden NKV-550 Series Ventilator System (K181695)	Proposed Device: HAMILTON-G5	Comparison
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
Modes of ventilation	• A/CMV-PC • A/CMV-VC • A/CMC-PRVC • SIMV-PC-PS • SIMV-VC-PS • SIMV-PRVC-PS • SPONT-CPAP • SPONT-PS • SPONT-VS • APRV • nCPAP	• ASV • APVcmv • APVsimv • P-CMV • P-SIMV • SPONT • DuoPAP • APRV • (S)CMV • SIMV • VS • nCPAP-PS • NIV • NIV-ST	Substantially equivalent
Alarms, adjustable	• Airway Pressure (Paw), High • Minute Ventilation (MV), High/Low • Low/high tidal volume • Low/high SpO2 • Low/High Pulse rate • High respiratory rate • Apnea • High/Low EtCO2	• Low/high minute volume • Low/high pressure • Low/high tidal volume • Low/high respiratory rate • Apnea time • PetCO2, low/high • Low/high pulse • Low/high SpO2 • Low/high SpMet • Low/high SpOC • % leak	Substantially Equivalent
Chemicals Delivered to Patient	• Medical Air and Oxygen	• Medical Air and Oxygen (Optional Heliox)	Substantially Equivalent
Delivery method to Patient	• Positive pressure	• Positive pressure	Same
Energy Used for Device	• AC Power and DC Power (battery)	• AC Power and DC Power (battery)	Same
Therapy Types	• Invasive, Non-invasive, O_2 Therapy (High flow)	• Invasive, Non-invasive, cFlow (High flow)	Same

IX. 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 were completed 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-G5, with the new features, was conducted. The new therapy cFlow was subjected to comparison testing with legally marketed devices. 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 K131774) 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-G5 ventilator is substantially equivalent to the legally marketed devices identified herein.