December 11, 2020

Hamilton Medical AG
Annemarie Weideli
Team Leader Regulatory Affairs
Via Crush 8
Bonaduz, GR 7402
Switzerland

Re: K201658
Trade/Device Name: Hamilton-C6
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: November 10, 2020
Received: November 13, 2020

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 J. Lee
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201658

Device Name
HAMILTON-C6

Indications for Use *(Describe)*
The HAMILTON-C6 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-C6 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.

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HAMILTON MEDICAL
Intelligent Ventilation since 1983

HAMILTON-C6

510(k) SUMMARY

I. SUBMITTER

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Contact Person: Annemarie Weideli, Team Leader Regulatory Affairs

Date Prepared: 2020-11-09

II. DEVICES

Name of Devices: HAMILTON-C6
Common or Usual Name: Continuous ventilator
Regulation Number and Name: Ventilator, Continuous (21 CFR 868.5895)
Device Classification: 2
Product Code: CBK (subsequent: DQA)

III. PREDICATE DEVICE

HAMILTON-C3 (K161450)

IV. REFERENCE DEVICES

HAMILTON-G5 (K193228)

V. DEVICE DESCRIPTION

The HAMILTON-C6 is designed for adult, pediatric, infant, and neonatal patients requiring invasive or noninvasive ventilation support. It covers a full range of clinical requirements, including invasive ventilation, automated ventilation with Adaptive Support Ventilation (ASV), and noninvasive ventilation.
The HAMILTON-H900 and IntelliCuff control options for the HAMILTON-C6 allow the remote control of the HAMILTON-H900 humidifier and IntelliCuff cuff pressure controller through the HAMILTON-C6 ventilator.

VI. INDICATIONS FOR USE

The HAMILTON-C6 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-C6 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. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICES

A comparative summary of the technological characteristics of the HAMILTON-C6 with the predicate and reference devices is presented below.

Table 1: Comparison of HAMILTON-C6 with predicate and reference device

Parameters	Proposed device: HAMILTON-C6	Predicate device: Currently marketed HAMILTON-C3	Reference device: Currently marketed HAMILTON-G5	Comparison
Intended use	The HAMILTON-C6 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-C6 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-C3 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-C3 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-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 healthcare 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
Product classification code	CBK (subsequent: DQA)	CBK (subsequent: DQA)	CBK (subsequent: DQA)	Equivalent
CFR citation	21 CFR 868.5895	21 CFR 868.5895	21 CFR 868.5895	Equivalent
Principal operator	Qualified, trained personnel under the direction of a physician	Qualified, trained personnel under the direction of a physician	Qualified, trained personnel under the direction of a physician	Equivalent

Parameters	Proposed device: HAMILTON-C6	Predicate device: Currently marketed HAMILTON-C3	Reference device: Currently marketed HAMILTON-G5	Comparison
Environment of use	Intended areas of use: • Health care facilities • During transfer of ventilated patients within health care facilities	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	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	Equivalent
Intended patient population	Adults, pediatrics, infants and neonates	Adults, pediatrics, infants and neonates	Adults, pediatrics, infants and neonates	Equivalent
Patient interface	Delivered invasively (via ET tube) or noninvasively (via mask)	Delivered invasively (via ET tube) or noninvasively (via mask)	Delivered invasively (via ET tube) or noninvasively (via mask)	Equivalent
Power source	AC, Battery	AC, DC, Battery	AC, Battery	Substantially Equivalent
Operational modes	• (S)CMV (only for adult/pediatric patients) • SIMV (only for adult/pediatric patients) • APVcmv / (S)CMV+ • APVsimv / SIMV+ • PCV+ • PSIMV+ • DuoPAP • APRV • SPONT • ASV (only for adult/pediatric patients) • NIV • NIV-ST • nCPAP-PS (only for neonatal patients)	• (S)CMV (only for adult/pediatric patients) • SIMV (only for adult/pediatric patients) • APVcmv / (S)CMV+ • APVsimv / SIMV+ • PCV+ • PSIMV+ • DuoPAP • APRV • SPONT • ASV (only for adult/pediatric patients) • NIV • NIV-ST • nCPAP-PS (only for neonatal patients)	• (S)CMV (only for adult and pediatric patients) • SIMV (only for adult and pediatric patients) • APVcmv • APVsimv • P-CMV • P-SIMV • DuoPAP • APRV • SPONT • VS • ASV (only for adult and pediatric patients) • NIV (only for adult and pediatric patients) • NIV-ST (only for adult and pediatric patients) • nCPAP-PS (only for neonatal patients)	Substantially Equivalent
Therapy Types	• Invasive, Non-invasive, HiFlowO2	• Invasive, Non-invasive	• Invasive, Non-invasive, HiFlowO2	Substantially Equivalent
Electrical safety	IEC 60601-1: 2005 (3rd Edition): all applicable requirements met.	IEC 60601-1: 2005 (3rd Edition): all applicable requirements met.	IEC 60601-1: 2005 (3rd Edition): all applicable requirements met.	Equivalent

Parameters	Proposed device: HAMILTON-C6	Predicate device: Currently marketed HAMILTON-C3	Reference device: Currently marketed HAMILTON-G5	Comparison
Emergency air intake	In case of a power supply, technical, or pneumatics failure the ambient valve allows spontaneous breathing.	In case of a power supply, technical, or pneumatics failure the ambient valve allows spontaneous breathing.	In case of a power supply, technical, or pneumatics failure the ambient valve allows spontaneous breathing.	Equivalent
Active exhalation valve?	Yes, pneumatic	Yes, pneumatic	Yes, pneumatic	Equivalent
Alarms and monitoring	Yes	Yes	Yes	Equivalent
Supply gas	Oxygen, ambient air	Oxygen, ambient air	Oxygen, Air, Heliox	Substantially Equivalent
Method of supply gas pressurization	Internal turbine for air, compressed source for O2	Internal turbine for air, compressed source for O2	Compressed source for Air, O2, Heliox	Substantially Equivalent
CO2 monitoring option	Yes	Yes	Yes	Equivalent
SpO2 monitoring option	Yes	Yes	Yes	Equivalent

As can be seen in Table 1 above, the proposed device HAMILTON-C6 has the same technological characteristics as the predicate HAMILTON-C3.
Altogether, the technological characteristics of the proposed device HAMILTON-C6 are substantially equivalent to the predicate devices. Thus, the comparison of the HAMILTON-C6 to its predicate device does not raise new safety and effectiveness concerns.

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-C6 operates as intended.

In particular, testing demonstrated that the HAMILTON-C6 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
- 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 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 62304 (2015): Medical device software - Software life-cycle processes

- IEC 62366 (2008)+A1(2014): Medical devices - Application of usability engineering to medical devices
- ISO 80601-2-12 (2011): Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators
- 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 Standard 7351731 - Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers
- AAMI / ANSI HE75:2009,Human factors engineering - Design of medical devices

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 HAMILTON-C6 was conducted. The ventilation modes were subjected to waveform performance testing. The data provided from these tests was shown to be substantially equivalent to the legally marketed devices.

IX. BIOCOMPATIBILITY

The gas pathway of the HAMILTON-C6 was evaluated according to ISO 18562 series. The materials have been evaluated and found to be acceptable for the intended use, intended patient population, and type of patient contact.

X. SUMMARY OF CLINICAL TESTING

No clinical testing was conducted or required in support of this premarket notification.

XI. CONCLUSION

Substantial equivalence has shown similar technological characteristics, intended use, principles of operation and verification and validation. The proposed device HAMILTON-C6 has software and hardware enhancements to maintain the intended performance of the device.

No new questions of safety and effectiveness have been raised. The HAMILTON-C6 ventilator is as safe and as effective as the legally marketed devices identified herein. From the evidence presented in the premarket notification, the proposed device can be considered substantially equivalent to the predicate devices.