DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 27, 2017

Hamilton Medical AG
Annemarie Höft
Quality Engineer
Via Crusch 8
Bonaduz, 7402
SWITZERLAND

Re: K161450
Trade/Device Name: Hamilton-C3
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK, DQA
Dated: March 20, 2017
Received: March 23, 2017

Dear Ms. Höft:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161450

Device Name
HAMILTON-C3

Indications for Use *(Describe)*
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.

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·C3

510(k) SUMMARY

I. SUBMITTER

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Contact Person: Annemarie Höft, Quality Engineer
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Date Prepared: 2017-04-24

II. DEVICE

Name of Devices: HAMILTON-C3
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 DEVICES

HAMILTON-C3 (K123637)
HAMILTON-G5 (K131774)

IV. DEVICE DESCRIPTION

The HAMILTON-C3 is designed for adult, paediatric, 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 510(k) submission intends to add the following new features to the previously cleared ventilator HAMILTON-C3:

- The following two new ventilation modes for adult / pediatric patient group: (S)CMV and SIMV
- SpO2 monitoring option

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICES

A comparative summary of the technological characteristics of the HAMILTON-C3 with the primary predicate and reference devices is presented below.

Table 1: Comparison of HAMILTON-C3 with predicate device

Parameters	Application device: HAMILTON-C3	Predicate device: Currently marketed HAMILTON-C3	Predicate device: Currently marketed HAMILTON-G5	Comparison
Intended use	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	The HAMILTON-C3 ventilator is intended to provide positive pressure ventilatory support to adults, paediatrics, infants, and neonates. Intended areas of use: • In the intensive care ward 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 paediatric 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	Substantially equivalent

	specifications.		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.	
Product classification code	CBK (subsequent: DQA)	CBK	CBK (subsequent: DQA)	Substantially Equivalent
CFR citation	21 CFR 868.5895	21 CFR 868.5895	21 CFR 868.5895	Substantially 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	Substantially Equivalent *Same principal operator as on HAMILTON-C3 and HAMILTON-G5*
Environment of use	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 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	Substantially Equivalent *Same environment of us as on HAMILTON-C3 and HAMILTON-G5*
Intended patient population	Adults, pediatrics, infants and neonates	Adults, pediatrics, infants and neonates	Adults, pediatrics, infants and neonates	Substantially Equivalent *Same Intended patient population as on HAMILTON-C3 and HAMILTON-G5*

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)	Substantially Equivalent *Same patient interface as on HAMILTON-C3 and HAMILTON-G5*
Power source	AC, DC, Battery	AC, DC, Battery	AC, Battery	Substantially Equivalent *Power source is unchanged.*
Operational modes	• PCV+ • SPONT • APVcmv / (S)CMV+ • APVsimv / SIMV+ • ASV (only for adult/pediatric patients) • PSIMV+ • DuoPAP • APRV • NIV • NIV-ST • nCPAP-PS (only for neonatal patients) • **(S)CMV (only for adult/pediatric patients)** • **SIMV (only for adult/pediatric patients)**	• PCV+ • SPONT • (S)CMV+ • SIMV+ • ASV (only for adult/pediatric patients) • PSIMV+ • DuoPAP • APRV • NIV • NIV-ST • nCPAP-PS (only for neonatal patients)	• (S)CMV (only for adult and pediatric patients) • P-CMV • SIMV (only for adult and pediatric patients) • P-SIMV • SPONT • APVcmv • APVsimv • ASV (only for adult and pediatric patients) • DuoPAP • APRV • NIV (only for adult and pediatric patients) • NIV-ST (only for adult and pediatric patients) • nCPAP-PS (only for neonatal patients) • VS	Substantially Equivalent
Electrical safety	IEC 60601-1: 2005 (3rd Edition): all applicable requirements met.	IEC 60601-1:1988 (A1:1991 + A2:1995): all applicable requirements met.	IEC 60601-1: 2005 (3rd Edition): all applicable requirements met.	Substantially Equivalent
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.	Substantially Equivalent *Same emergency air intake as on HAMILTON-C3 and HAMILTON-G5*

Active exhalation valve?	Yes, pneumatic	Yes, pneumatic	Yes, pneumatic	Substantially Equivalent *Active exhalation is unchanged.*
Alarms and monitoring	Yes	Yes	Yes	Substantially 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	Substantially Equivalent *CO2 monitoring is unchanged.*
SpO2 monitoring option	Yes	No	Yes	Substantially Equivalent
Differences in technological characteristics	- Embedded system type: EM10A	- Embedded system type: EM10A	- Embedded system type: EM01A	Substantially Equivalent
	- Internal flow sensor with the ability to detect reflow	- Internal flow sensor without the ability to detect reflow	- Internal flow valve without the ability to detect reflow	
	- Flashing alarm lamp	- Alarm lamp not flashing, only illuminated	- Flashing alarm lamp	

As can be seen in the table above, the application device HAMILTON-C3 has the same technological characteristics as the predicate HAMILTON-C3, with the exception of its internal flow sensor. The applicant device HAMILTON-C3 add new (S)CMV and SIMV ventilation mode which have same algorithms for delivering breaths as the predicate device HAMILTON-G5.
Altogether, the technological characteristics of the application device HAMILTON-C3 are substantially equivalent to the predicate devices. Thus, the comparison of the HAMILTON-C3 to its predicate devices does not raise new safety and effectiveness concerns.

VII. 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-C3 operates as intended.

In particular, testing demonstrated that the HAMILTON-C3 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 (2008)+A1(2014): Medical devices - Application of usability engineering to 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 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 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-C3, with the new features, was conducted. The new 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.

Since only materials already used in earlier 510(k)s are introduced with this 510(k), Hamilton Medical did not conduct any additional biocompatibility testing.

VIII. CONCLUSION

The results of verification, validation, and testing activities demonstrate that the modified HAMILTON-C3 ventilator is as safe and as effective as the legally marketed devices identified herein.