Hamilton Medical AG
Simone Haller
Regulatory Affairs Specialist
Via Crusch 8
Bonaduz, GR 7402
Switzerland

Re: K201306
Trade/Device Name: Hamilton-C3
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: January 5, 2021
Received: January 7, 2021

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,

Brandon Blakely, PhD
Acting 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201306

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.
Intende 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

I. SUBMITTER

Hamilton Medical AG
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Contact Person: Timo Tscharntke, Regulatory Affairs Specialist

Date prepared: 2020-02-05

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 (secondary: DQA)

III. PREDICATE DEVICES

- Primary predicate device for the ventilator HAMILTON-C3 itself: HAMILTON-C3 (K161450) (Company Hamilton Medical AG)

IV. REFERENCE DEVICE

- Reference device regarding introduced therapy type HiFlowO2: HAMILTON-G5 (K180295) (Company Hamilton Medical AG)

V. DEVICE DESCRIPTION

The **HAMILTON-C3** 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 510(k) submission intends to add the following new features to the previously cleared ventilator HAMILTON-C3:

- Therapy type: HiFlowO2

VI. INDICATIONS FOR USE

- **Ventilator HAMILTON-C3**
  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.

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

A comparative summary of the technological characteristics of the HAMILTON-C3 with the primary predicate and the predicate device is presented in the tables below.

Table 1: Comparison of HAMILTON-C3 with the primary predicate device

Parameters	Subject device: HAMILTON-C3	Primary predicate device: Currently marketed HAMILTON-C3	Comparison
Indication for use	The HAMILTON-C3 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. • 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-C3 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. • 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.	Same
Modes of ventilation	• (S)CMV (only for adult/pediatric patients) • APVcmv / (S)CMV+ • SIMV (only for adult/pediatric patients) • APVsimv / SIMV+ • PCV+ • PSIMV+ • DuoPAP • APRV • SPONT and NIV • NIV ST • nCPAP-PS (only for neonatal patients) • ASV (only for adult/pediatric patients)	• (S)CMV (only for adult/pediatric patients) • APVcmv / (S)CMV+ • SIMV (only for adult/pediatric patients) • APVsimv / SIMV+ • PCV+ • PSIMV+ • DuoPAP • APRV • SPONT and NIV • NIV ST • nCPAP-PS (only for neonatal patients) • ASV (only for adult/pediatric patients)	Same
Therapy type	• High Flow O2 (HiFlowO2) • Control settings (ranges), adult: Flow (2 to 60 l/min) • Control settings (ranges), neonatal: Flow (2 to 12 l/min) • Control settings (defaults), adult: Flow (15 l/min) • Control settings (defaults), neonatal: Flow (2 l/min)	---	please refer to Table 2

Hamilton Medical AG has demonstrated the proposed HAMILTON-C3 ventilator to be substantial equivalent to the currently marketed (here primary predicate device) HAMILTON-C3 (K161450) that has been previously cleared by FDA.

Table 2: Comparison of HAMILTON-C3 with the reference device

Parameters	Subject device: HAMILTON-C3	Reference device: HAMILTON-G5	Comparison
Intended use	The HAMILTON-C3 ventilator is intended to provide positive pressure ventilatory support to adults, pediatrics, infants and neonates depending on its configuration. 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 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	The device is intended for use in the hospital and institutional environment where healthcare professionals provide patient care	The device is intended for use in the hospital and institutional environment where healthcare professionals provide patient care	Same
Anatomical site	Patient airways	Patient airways	Same
Target population	Adult, pediatric and neonatal patients	Adult, pediatric and neonatal patients	Same
HiFlowO2 flow range and settings	*Range* • 2 to 12 l/min (neonatal) • 2 to 60 l/min (adult/pediatric) *Settings* • Flow adult/pediatric: 15 l/min • Flow neonatal: 2 l/min • Oxygen adult/pediatric: 50 % • Oxygen neonatal: 40 %	*Range* • 1 to 12 l/min (neonatal) • 1 to 60 l/min (adult/pediatric) *Settings* • Flow adult/pediatric: 15 l/min • Flow neonatal: 1 l/min • Oxygen adult/pediatric: 50 % • Oxygen neonatal: 40 %	Similar
Alarms, adjustable	• High oxygen • Low oxygen	• High oxygen • Low oxygen	Same
Alarms, non-adjustable	• Check for blockage	• Check for blockage • Cannot reach target flow	Different

Parameters	Subject device: HAMILTON-C3	Reference device: HAMILTON-G5	Comparison
Chemicals delivered to patient	Medical air and oxygen	Medical air and oxygen[1]	Same
Delivery method to patient	Positive pressure	Positive pressure	Same
Energy used for device	AC, DC, battery	AC, battery	Different
Therapy types	Invasive, non-invasive, HiFlowO2	Invasive, non-invasive, HiFlowO2	Same
Performance test	A bench test with a comparison of the HiFlowO2 performance is submitted.		Substantially equivalent

The subject device HAMILTON-C3 is compared to the reference device HAMILTON-G5 regarding the introduced therapy type HiFlowO2, which resulted in substantial equivalence with respect to the HiFlowO2 therapy type (Table 2).

[1] Optional Heliox

VIII. PERFORMANCE DATA

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

HAMILTON-C3

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 Part 1 General requirements for basic safety and essential performance
- IEC 60601-1:2005 3rd Edition US National deviations
- 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
- 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 (2018): Medical electrical equipment -- Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors
- ISO 80601-2-61 (2018): Medical electrical equipment -- Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- IEC 80601-2-49 (2018): Medical electrical equipment – Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- IEC 62304 (2015): Medical device software - Software life-cycle processes
- IEC 62366 (2008)+A1(2014): Medical devices - Application of usability engineering to medical devices
- AIM Standard 7351731 - Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers

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, the therapy type HiFlowO2, was conducted by a bench test comparing the flow and oxygen values. The data provided from this test was shown to be substantially equivalent to the legally marketed predicate device.

Since only materials in relation to the ventilator itself, which are already used in in the primary predicate (cleared under document number K161450) are used (the new features did not include any material changes, only software adaptions), Hamilton Medical AG did not conduct any additional biocompatibility testing.

IX. CONCLUSION

The results of verification, validation, and testing activities demonstrate that the modified HAMILTON-C3 ventilator is substantially equivalent to the legally marketed primary predicate device and substantially equivalent to the reference device (with respect to the new feature HiFlowO2) identified herein.