HAMILTON MEDICAL

HAMILTON·C1

MAY 3 0 2012

510(k) SUMMARY

SUBMITTER:	HAMILTON MEDICAL AG Via Crusch 8 Bonaduz, 7402 SWITZERLAND
CONTACT PERSON:	Ralph Aguila Regulatory Affairs / Quality Engineer Phone: +41 81 660 6845 Fax: +41 81 660 6020 e-mail: raguila@hamilton-medical.ch
ESTABLISHMENT REGISTRATION NUMBER:	3001421318
PREPARATION DATE:	2012-04-19
TRADE NAME:	HAMILTON-C1
COMMON NAME:	Continuous Ventilator
CLASSIFICATION NAME:	CLASS II Ventilator, Continuous
REGULATION NUMBER:	21 CFR 868.5895
PRODUCT CODE:	CBK
PREDICATE DEVICE:	HAMILTON-T1 510(k) Number: K112006

DEVICE DESCRIPTION

The HAMILTON-C1 is designed for adults and pediatrics requiring invasive or noninvasive ventilation support. The HAMILTON-C1 ventilator covers a full range of clinical requirements: including invasive ventilation, automated ventilation with Adaptive Support Ventilation (ASV), and Non-Invasive Ventilation (NIV).

The HAMILTON-C1 is suitable for ICU special-care areas, cardiac surgery recovery rooms, stepdown or sub-acute care units, and long-term care centers. With its IntelliTrig technology, the HAMILTON-C1 responds to the changing breathing patterns or circuit leaks found in non-invasive ventilation by automatically varying leaks and adapting sensitivity thresholds for optimal response to the patient's breath.

The HAMILTON-C1's software and ventilation modes are identical to the HAMILTON-T1's software and ventilation modes. One can operate the HAMILTON-C1 with the touchscreen or with a single turn wheel. Hard keys give direct access to the most important functions. In effect, the HAMILTON-C1 is a HAMILTON-T1, but with the features related to transport-ventilation stripped off.

With the large alarm lamp, a clinician can immediately identify an alarming HAMILTON-C1 ventilator because of the alarm lamp located at the top of the device, even if the clinician is at a long distance away or when several different devices are operating simultaneously in the same room.

Interface for PDMS, patient monitor, and nurse call are available as well. The optional interfaces provide ports for connection to hospital monitors, Patient Data Management Systems (PDMS), and nurse call systems.

The high-performance turbine can deliver up to 210 L/min flow; this relatively high flow rate is potentially helpful when utilizing NIV modes of ventilation.

INTENDED USE

The HAMILTON-C1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics.

Intended areas of use:

- In the intensive care ward or in the recovery room.
- During transfer of ventilated patients within the hospital.

The HAMILTON-C1 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.

DISCUSSION ON THE NON-CLINICAL TESTS

The non-clinical test results show that the HAMILTON-C1 is safe and effective for its intended use. Below is a list of standards and guidance documents recognized by FDA to establish the basis of safety and effectiveness for the HAMILTON-C1. These standards are the exact ones used by the HAMILTON-T1 for its 510(k) clearance, except for the transport-related standards, such as the RTCA/DO 160F, which the HAMILTON-C1 is not designed for. The results of the following non-clinical tests support a determination of substantial equivalence. In addition, the conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs just as well as the predicate device.

	Draft Reviewer Guidance for Ventilators.1995.
IEC 60601-1	General Requirements for Safety.
IEC 60601-1-2	Electromagnetic Compatibility.
IEC 60601-1-4	Programmable electrical medical systems.
IEC 60601-1-8	Alarm Systems
IEC 60601-2-12	Critical Care Ventilators.
IEC 62304	Software life-cycle processes.
IEC 62366	Application of usability engineering to medical devices.
ISO 5356-1	Conical connectors: Part 1: Cones and sockets.
AAMI/ANSI HE75	Human factors engineering. Design of medical devices.
EN ISO 14971	Application of risk management to medical devices.

Other internationally recognized standards which the HAMILTON-C1 meets or exceeds:

EN ISO 13485	Medical devices -- Quality management systems.
EN ISO 9001	Quality management systems.
EN ISO 5359	Low-pressure hose assemblies for use with medical gases.
EN 794-1	Particular requirements for critical care ventilators.
IEC 62133	Battery Safety. Non-Spillable.
ASTM F1100-90	Standard Specification for Ventilators Intended for Use in Critical Care.
MIL-STD-461E	RS101, CS114 (curve #3), and RE101 (Army 7-cm limit).

COMPARISON WITH THE PREDICATE DEVICE

	HAMILTON-T1 Predicate device: K112006	HAMILTON-C1 Proposed device: K120574	COMMENTS
Intended Use	The HAMILTON-T1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics. Intended areas of use: • In the intensive care ward or in the recovery room. • For emergency medical care or primary care. • During transport within and outside the hospital. • During transfer by rescue vehicles, jet or helicopter. The HAMILTON-T1 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-C1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics. Intended areas of use: • In the intensive care ward or in the recovery room. • During transfer of ventilated patients within the hospital. The HAMILTON-C1 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 only major difference between the HAMILTON-C1 and the HAMILTON-T1 is the transport aspect. Because of the different environment of use, the enclosure for the HAMILTON-T1 has been ruggedized in accordance with the RTCA/DO 160F to withstand shock, vibrations, water ingress, and drops from >1 meter heights. The HAMILTON-C1 is not designed for such an environment of use. The HAMILTON-C1 only has one battery, compared to the two batteries found on the HAMILTON-T1. The HAMILTON-T1 has a DC-power inlet and can withstand greater temperature extremes. The HAMILTON-T1 also has extra safety features compared to the HAMILTON-C1 for the EMD, ESD, and RFI environments found on aircraft. In all other respects, however, the HAMILTON-C1 is exactly the same as the HAMILTON-T1.
Intended Patient Population	Patients include adults and pediatrics.	Patients include adults and pediatrics.	The HAMILTON-C1 is equivalent.

Maximum Inspiratory Flow	210 l/min	210 l/min	Equivalent
Is it airworthy?	Yes	No	The HAMILTON-C1 is not designed for air transport.
Water Protection	IPX4	IPX1	The HAMILTON-T1 has greater protection against water ingress for the transport environment.
Temperature Range	–15 to 40 °C (operating), –15 to 70 °C (storage)	5 to 40 °C (operating), –20 to 60 °C (storage)	The HAMILTON-T1 has a greater tolerance of wider temperature variances for the transport environment.
Software version	Version 1.1.2	Version 1.1.2	Equivalent
Number of batteries	2	1	The HAMILTON-T1 has an additional battery.
Weight	6.5 kg (14.3 lb) with 2 batteries and a handle	4.9 kg (10.8 lb) without trolley	The HAMILTON-C1 is lighter in weight.

The intended use statement for the HAMILTON-C1 ventilator is comparable to the predicate device. The only difference is that the HAMILTON-C1 has a more limited intended use due to the fact that it is not hardened for transport environments. However, the technological characteristics (i.e., design, material, energy source) and performance specifications of the HAMILTON-C1 ventilator are equivalent to those of the predicate device. The HAMILTON-C1 meets all the standards set by FDA for non-transport ventilators. The differences do not affect the safety and effectiveness of the device when used as labeled.

The intended use of the HAMILTON-C1 is covered by the referenced predicate device. The technical characteristics of the HAMILTON-C1 do not raise any new questions regarding the safety or effectiveness of ventilators. The HAMILTON-C1's software has gone through verification/validation tests. A complete revision level history, hazard analysis, and a traceability analysis linking requirements to validation were done. The conclusions drawn from the non-clinical tests demonstrate that the HAMILTON-C1 is as safe, as effective, and performs as well as the legally marketed device. The differences are not critical to the intended therapeutic use of the device. The HAMILTON-C1 is, therefore, considered to be substantially equivalent to the currently marketed predicate device which has been previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Ralph Aguila
Quality Engineer, Regulatory Affairs
Hamilton Medical AG
Via Crusch 8
Bonaduz, 7402
SWITZERLAND

MAY 30 2012

Re: K120574
Trade/Device Name: HAMILTON-C1
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: April 19, 2012
Received: May 7, 2012

Dear Mr. Aguila:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: _____

Device Name: HAMILTON-C1

Indication for Use: The HAMILTON-C1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics.
Intended areas of use:

- In the intensive care ward or in the recovery room.
- During transfer of ventilated patients within the hospital.

The HAMILTON-C1 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.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K120574