K121228

HAMILTON MEDICAL

HAMILTON·C2

510(k) SUMMARY

NOV 16 2012

SUBMITTER:	HAMILTON MEDICAL AG Via Crusch 8 Bonaduz, Grisons 7402 SWITZERLAND
CONTACT PERSON:	Ralph Aguila Regulatory Affairs / Quality Engineer Phone: +41 81 660 6845 Fax: +41 81 660 6020 e-mail: raaguila@hamilton-medical.ch
ESTABLISHMENT REGISTRATION #:	3001421318
PREPARATION DATE:	2012-10-23
TRADE NAME:	HAMILTON-C2
COMMON NAME:	Continuous Ventilator
CLASSIFICATION NAME:	Class II Ventilator, Continuous
REGULATION NUMBER:	21 CFR 868.5895
PRODUCT CODE:	CBK
PREDICATE DEVICE: (PRIMARY)	HAMILTON-C2 (**K102775**)
PREDICATE DEVICES: (SECONDARY)	HAMILTON-G5 (**K103803**), HAMILTON-T1 (**K120670**), Draeger's Infinity Acute Care System Workstation - Neonatal Care (**K093632**).

DEVICE DESCRIPTION

The HAMILTON-C2 has been designed to ventilate adult and pediatric patients in the critical care environment. With optional support, the HAMILTON-C2 is also able to ventilate infants and neonates. The HAMILTON-C2 ventilator uses the same graphical user interface (GUI) used by the HAMILTON-C2, HAMILTON-G5, and HAMILTON-T1, which features a touchscreen "Ventilation Cockpit'. This provides the exact information that the user needs and helps focus on what is important. In addition, the HAMILTON-C2 includes the ASV ventilation-mode, which automatically applies lung-protective strategies, reduces the risk of operator error, and promotes early weaning.

The HAMILTON-C2 has been designed with built-in batteries and a turbine thereby giving the user maximum independence and flexibility to accompany a patient everywhere. The HAMILTON-C2 offers ventilation modes that provide full and partial ventilatory support.

1. The HAMILTON-C2 offers all the conventional modes, as well as advanced invasive and non-invasive ventilation modes: ASV, (S)CMV+, SIMV+, PCV+, SPONT, APRV, DuoPAP, NIV, NIV-ST, nCPAP-PS, PSIMV+ with IntelliSync, and PSIMV+ without IntelliSync.

2. All 41 monitoring parameters can be trended over 1, 6, 12, 24, and 72 hours.

3. The new HAMILTON-C2 offers the mode option of both "PSIMV+ with IntelliSync" and "PSIMV+ without IntelliSync". In the previously cleared version of the HAMILTON-C2, the only version of PSIMV+ that was included had IntelliSync.

4. The ability to turn off the Apnea alarm in the nCPAP-PS mode.

5. Because some clinicians prefer to set the rate and the inspiration time Ti and other clinicians prefer to set the rate and the inspiration-expiration ratio I:E to define the timing of mandatory breaths in controlled modes. Therefore, both options are available in the proposed HAMILTON-C2

INTENDED USE

The HAMILTON-C2 ventilator is intended to provide positive pressure ventilatory support to adults, pediatrics, infants, and neonates.

Intended areas of use:

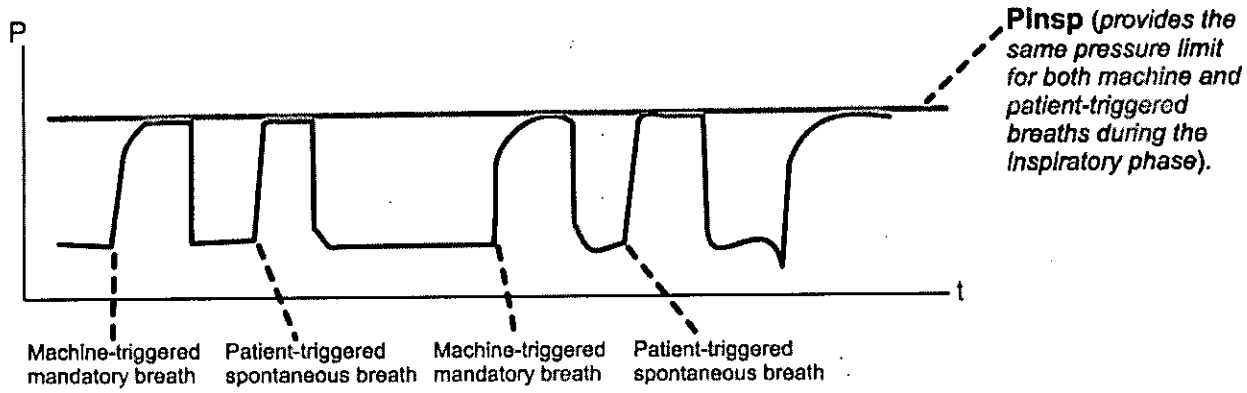
- In the intensive care ward or in the recovery room.
- During transfer of ventilated patients within the hospital.

The HAMILTON-C2 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.

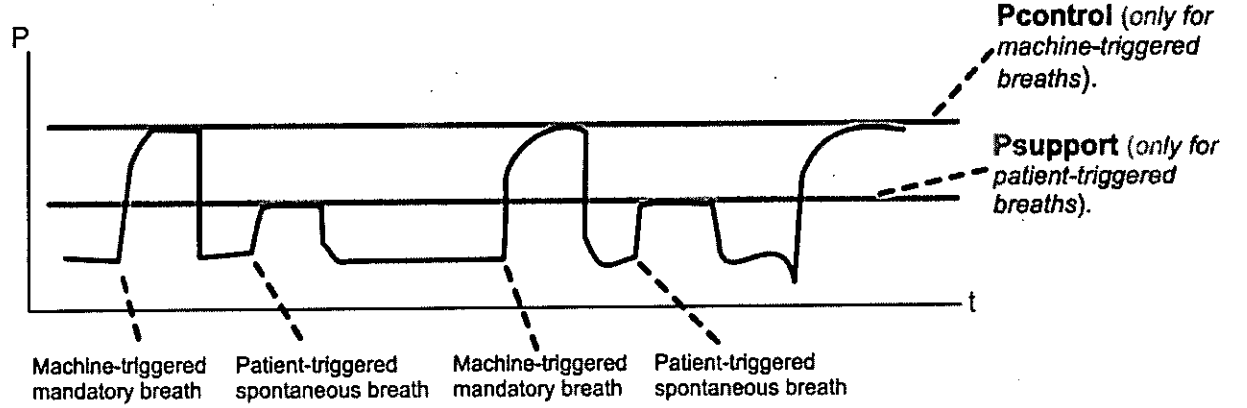
SUMMARY OF THE TECHNOLOGY AND PERFORMANCE SPECIFICATIONS COMPARISON WITH THE PREDICATE DEVICES

The intended use statement for the modified HAMILTON-C2 ventilator is substantially equivalent to that of the primary predicate device. The technological characteristics (i.e., design, material, energy source) and performance specifications of the proposed HAMILTON-C2 ventilator are substantially equivalent to those of the predicate devices. HAMILTON MEDICAL has demonstrated the proposed HAMILTON-C2 ventilator to be as safe and effective as the predicate devices.

PSIMV+ with IntelliSync is a mode that delivers pressure-controlled, time-cycled mandatory breaths and pressure supported, flow-cycled spontaneous breaths. As with the PCV+ mode, PSIMV+ with IntelliSync delivers a preset pressure, but does not guarantee a fixed tidal volume, especially during changes in respiratory system compliance, airway resistance, Auto-PEEP, or the patient's respiratory activity. The graphic below illustrates this principle:



For PSIMV+ without IntelliSync, the mandatory breaths are PCV+ breaths which can be alternated with SPONT breaths. PSIMV+ without IntelliSync does not guarantee the delivery of an adequate tidal volume at all times. Therefore, when using this mode, the operator must carefully monitor changes in the patient's status. The following graphic illustrates the previous points:



Lastly, nCPAP-PS is designed to apply nasal continuous positive airway pressure with additional pressure support to infants and neonates. With the new version of the HAMILTON-C2, the operator has the ability of turning off the apnea alarm in the nCPAP-PS mode. However, the minimum respiratory rate for patients in this mode remains 15 b/min to 150 b/min.

DISCUSSION ON THE NON-CLINICAL PERFORMANCE TESTS

The non-clinical test results show that the HAMILTON-C2 is safe and effective for its intended use. The HAMILTON-C2 was further subjected to waveform performance testing as described in the standard ASTM F1100-90. The results of the software verification and validation testing demonstrate that all specified requirements have been implemented correctly and completely.

Below is a list of standards and guidance documents recognized by FDA to establish the basis of safety and effectiveness for the HAMILTON-C2:

	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.
ISO 14971	Application of risk management to medical devices.

CONCLUSION

A complete revision level history, hazard analysis, and a traceability analysis linking requirements to validation were done. The results of foregoing tests, along with the necessary verification and validation tests, demonstrate that the modified HAMILTON-C2 ventilator is as safe, as effective, and performs just as well as the other legally marketed predicate devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Mr. Ralph Aguila
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Bonaduz, Grisons Switzerland 7402

NOV 16 2012

Re: K121225
Trade/Device Name: Hamilton-C2
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: October 23, 2012
Received: October 31, 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,

DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402

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Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K121225

Device Name: HAMILTON-C2

Indication for Use: The HAMILTON-C2 ventilator is intended to provide positive pressure ventilator support to adults, pediatrics, infants and neonates.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lester W. Schultheis Jr
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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K121225