K090468

HAMILTON MEDICAL

JUN 15 2009

# 510(k) Summary

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| **SUBMITTER:** | HAMILTON MEDICAL AG<br>Via Crusch 8<br>7402 Bonaduz, Switzerland |
| **CONTACT PERSON:** | Joerg Schneider<br>Phone: +41 81 660 64 79<br>Fax: +41 81 660 60 20<br>e-mail: jschneider@hamilton-medical.ch |
| **PREPARATION DATE:** | May 26, 2009 |
| **TRADE NAME:** | HAMILTON-C2 |
| **COMMON NAME:** | Continuous Ventilator |
| **CLASSIFICATION NAME:** | Ventilator, Continuous, Facility Use<br>(21 CFR 868.5895, Product Code: CBK) |
| **LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCE IS BEING CLAIMED:** | HAMILTON-G5<br>510(k) Number: K081521 |
| | Dräger SAVINA<br>510(k) Number: K023289 |

HAMILTON MEDICAL

## DEVICE DESCRIPTION

The HAMILTON-C2 is an electronically controlled pneumatic intensive care ventilator. Due to its compact design, a weight of only 9.5 kg, built-in, hot-swappable batteries, and an ultra-quiet turbine, this ventilator can accompany a patient everywhere within a hospital, independently of central gas and power supplies.

The device offers ventilation modes that provide full and partial ventilatory support. The ventilator's ergonomic design, including a 10.4 in. color touch screen, a press-and-turn knob, and keys, let the user access the ventilator settings and monitored parameters. The graphical user interface can be tilt up to 45°. The HAMILTON-C2 can be customized so that it starts up with institution-defined settings.

## INTENDED USE

The HAMILTON-C2 ventilator is intended to provide positive pressure ventilatory support to adults and paediatrics.

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 restricted 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 PREDICATED DEVICES

The indication statements for the HAMILTON-C2 ventilator are comparable to those for the predicate devices.

Technological characteristics and performance specifications of the HAMILTON-C2 ventilator are substantially equivalent to those of the predicate devices.

HAMILTON MEDICAL has demonstrated the HAMILTON-C2 ventilator to be safe and effective.

The HAMILTON-C2 is considered to be substantial equivalent to currently marketed predicate devices which have been previously cleared by FDA.

## NON-CLINICAL PERFORMANCE TESTS

Safety testing of the HAMILTON-C2 was conducted according to IEC60601-1, IEC60601-1-2, IEC 60601-2-12 and other applicable standards. The test results show that the device is safe and effective for its intended use. The ventilator was further subject to wave-form performance testing as described in the standard ASTM F1100-90. The data provided from these tests, were shown to be substantially equivalent to a legally marketed device. The results of the software verification and validation testing demonstrate that all specified requirements have been implemented correctly and completely.

## CONCLUSION

The results of verification, validation, and testing activities demonstrate that the HAMILTON-C2 ventilator is as safe, as effective, and performs as well as or better than the legally marketed devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 2009

Mr. Joerg Schneider
Quality Engineer
Hamilton Medical AG
Via Crush 8
Bonaduz 7402
SWITZERLAND

Re: K090468
Trade/Device Name: HAMILTON-C2
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: May 26, 2009
Received: June 15, 2009

Dear Mr. Schneider:

This letter corrects our substantially equivalent letter of June 15, 2009.

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 (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.

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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

# INDICATIONS FOR USE STATEMENT

510(k) Number: K090468

Device Name: HAMILTON-C2

Indication for Use: The HAMILTON-C2 ventilator is intended to provide positive pressure ventilatory support to adults and paediatrics.
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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultz

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

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