DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 6, 2016

Hamilton Medical AG
Katrin Vogt
Quality Engineer
Via Crusch 8
Bonaduz, Grisons, 7402
Switzerland

Re: K153046
Trade/Device Name: HAMILTON-MR1
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: CBK
Dated: August 5, 2016
Received: August 8, 2016

Dear Katrin Vogt:

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,

*Tejashri Purohit-Sheth, M.D.*

**Tejashri Purohit-Sheth, M.D.**
**Clinical Deputy Director**
**DAGRID/ODE/CDRH FOR**

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

# INDICATIONS FOR USE STATEMENT

510(k) Number: K153046

Device Name: **HAMILTON-MR1**

Indication for Use: The HAMILTON-MR1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.
Intended areas of use:

- In the MRI department
- 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-MR1 ventilator is classified as MR Conditional with the use of 1.5 Tesla and 3.0 Tesla static magnetic field scanners.

The HAMILTON-MR1 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___ | | Over-The-Counter Use _____ |
|---|---|---|
| (Part 21 CFR 801 Subpart D) | AND/OR | (21 CFR 801 Subpart C) |

Concurrence of CDRH, Office of Device Evaluation (ODE)

HAMILTON MEDICAL
Intelligent Ventilation since 1983

HAMILTON-MR1

# 510(k) SUMMARY

I. SUBMITTER

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Contact Person: Katrin Vogt, Quality Engineer
Date Prepared: 2016-09-05

II. DEVICE

Name of Devices: HAMILTON-MR1
Common or Usual Name: MRI department/ICU ventilator
Regulation Number and Name: Ventilator, Continuous (21 CFR 868.5895)
Device Classification: 2
Product Code: CBK

III. PREDICATE DEVICES

HAMILTON-MR1 (K122438)
HAMILTON-C1/T1 (K140939)

IV. DEVICE DESCRIPTION

The HAMILTON-MR1 is an MR-Conditional ventilator which increases the availability of appropriate modes of therapy for ventilated hospital patients requiring MR imaging. It 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. It can be used at the gauss line, in the presence of either 1.5T or 3T MRI machines.

With the shielded, MRI-compatible HAMILTON-MR1 ventilator, ventilation performance and MR image quality is as safe and as effective as the predicate device throughout the MRI procedure. The integrated gaussmeter is programmed to alarm when the clinician is placing the HAMILTON-MR1 too close to the MRI magnet, which helps the clinician to properly position the HAMILTON-MR1 at the 50mT (500 gauss) line or less.

The 510(k) submission intends to add the following new features to the previously cleared ventilator HAMILTON-MR1:

- Neonatal patients with a minimum weight of 0.2 kg and a minimal tidal volume of 2 mL
- The following two new modes for the neonatal patient group: nCPAP and nCPAP-PC

- An increase in the battery duration from 5 hours and 20 minutes to 9 hours and 20 minutes.

## V. INDICATIONS FOR USE

The HAMILTON-MR1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.
Intended areas of use:

- In the MRI department
- 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-MR1 ventilator is classified as MR Conditional with the use of 1.5 Tesla and 3.0 Tesla static magnetic field scanners.
The HAMILTON-MR1 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

The indication-of-use statement, for the modified HAMILTON-MR1 ventilator, has been adjusted to include infant and neonatal patients.

The new nCPAP and nCPAP-PC modes are substantially equivalent to those in the HAMILTON-C1/T1 ventilators.

**Table 1: Comparison of HAMILTON-MR1 with predicate device**

| Parameters | Application device: HAMILTON-MR1 | Predicate device: previous version of HAMILTON-MR1 | Predicate device: HAMILTON-C1 (K140939) |
|---|---|---|---|
| **Intended use** | The HAMILTON-MR1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.<br><br>Intended areas of use:<br>• In the MRI department<br>• In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital or in the recovery room<br>• During transfer of | The HAMILTON-MR1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics.<br><br>Intended areas of use:<br>• In the MRI department<br>• In the intensive care ward or in the recovery room<br>• During transfer of ventilated patients within the hospital<br><br>The HAMILTON-MR1 ventilator is classified as MR | The HAMILTON-C1 ventilator is intended to provide positive pressure ventilatory support to adults and pediatrics, and optionally infants and neonates.<br><br>Intended areas of use:<br>• In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital, or in the recovery room<br>• During transfer of |

| | | | |
|---|---|---|---|
| | ventilated patients within the hospital<br><br>The HAMILTON-MR1 ventilator is classified as MR Conditional with the use of 1.5 Tesla and 3.0 Tesla static magnetic field scanners. The HAMILTON-MR1 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. | Conditional with the use of 1.5 T and 3.0 Tesla static magnetic field scanners.<br><br>The HAMILTON-MR1 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. | ventilated patients within the hospital<br><br>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. |
| **Environment of use** | Intended areas of use:<br>• In the MRI department<br>• In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital, or in the recovery room<br>• During transfer of ventilated patients within the hospital | Intended areas of use:<br>• In the MRI department<br>• In the intensive care ward or in the recovery room<br>• During transfer of ventilated patients within the hospital | Intended areas of use:<br>• In the intensive care ward, intermediate care ward, emergency ward, long term acute care hospital, or in the recovery room<br>• During transfer of ventilated patients within the hospital |
| **Product classification code** | CBK | CBK | CBK |
| **CFR citation** | 21 CFR 868.5895 | 21 CFR 868.5895 | 21 CFR 868.5895 |
| **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 |
| **Intended patient population** | Patients include adults and pediatrics, and optionally infants and neonates. | Patients include adults and pediatrics. | Patients include adults and pediatrics, and optionally infants and neonates. |
| **Operational environmental requirements** | • 5°C to 40°C (41°F to 104°F)<br>• 10% to 95%, noncondensing<br>• 1100 to 700 hPa (9.842 ft) | • 5°C to 40°C (41°F to 104°F)<br>• 10% to 95%, noncondensing<br>• 1100 to 700 hPa | • 5 to 40 °C (41 to 104°F)<br>• 10 to 95%, non-condensing<br>• 1013 to 600 hPa |
| **Power source** | AC and battery powered with two batteries, can be run while batteries are charging. With a typical battery run time of 8 hours | AC and battery powered with two batteries, can be run while batteries are charging. With a typical battery run time of 5.5 hours | AC and battery powered with one battery, can be run while battery is charging with a maximal run time of 4.30 hours. |
| **Number of batteries** | 2 | 2 | 1 |

| | | | |
|---|---|---|---|
| **Supply gas** | Oxygen, ambient air | Oxygen, ambient air | Oxygen, ambient air |
| **Method of supply gas pressurization** | Internal turbine for air, compressed source for O2 | Internal turbine for air, compressed source for O2 | Internal turbine for air, compressed source for O2 |
| **Fresh gas intake filter** | • Monitored HEPA (High Efficiency Particulate Air filter):<br>• Alarm "Replace HEPA filter" in case of clogging.<br>• Yearly or every 5.000 h filter replacement specified. | • Monitored HEPA (High Efficiency Particulate Air filter):<br>• Alarm "Replace HEPA filter" in case of clogging.<br>• Yearly or every 5.000 h filter replacement specified. | • Monitored HEPA (High Efficiency Particulate Air filter):<br>• Alarm "Replace HEPA filter" in case of clogging.<br>Yearly or every 5.000 h filter replacement specified. |
| **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) |
| **Safety features** | • Apnea backup ventilation<br>• Automatic self-tests<br>• Alarms (operator-adjustable / non-adjustable)<br>• Alarm backup buzzer<br>• External flow sensor failure mode<br>• Safety mode in case of technical failures<br>• Air inlet HEPA filter monitoring<br>• Monitored fan<br>• Event log | • Apnea backup ventilation<br>• Automatic self-tests<br>• Alarms (operator-adjustable / non-adjustable)<br>• Alarm backup buzzer<br>• External flow sensor failure mode<br>• Safety mode in case of technical failures<br>• Air inlet HEPA filter monitoring<br>• Monitored fan<br>• Event log | • Apnea backup ventilation<br>• Automatic self-tests<br>• Alarms (operator-adjustable / non-adjustable)<br>• Alarm backup buzzer<br>• External flow sensor failure mode<br>• Safety mode in case of technical failures<br>• Air inlet HEPA filter monitoring<br>• Monitored fan<br>Event log |
| **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. |
| **Operational modes** | • ASV<br>• (S)CMV+<br>• SIMV+<br>• PCV+<br>• PSIMV+ (incl. the possibility to set IntelliSync to "Off")<br>• SPONT<br>• DuoPAP<br>• APRV<br>• NIV<br>• NIV-ST<br>• nCPAP<br>• nCPAP-PC | • ASV<br>• (S)CMV+<br>• SIMV+<br>• PCV+<br>• PSIMV+<br>• SPONT<br>• DuoPAP<br>• APRV<br>• NIV<br>• NIV-ST | • ASV<br>• (S)CMV+<br>• SIMV+<br>• PCV+<br>• PSIMV+ (incl. the possibility to set IntelliSync to "Off")<br>• SPONT<br>• DuoPAP<br>• APRV<br>• NIV<br>• NIV-ST<br>• nCPAP<br>• nCPAP-PC |
| **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. |
| **Active** | Yes, pneumatic | Yes, pneumatic | Yes, pneumatic |

| | | | |
|---|---|---|---|
| **exhalation valve?** | | | |
| **Volume setting range** | 2-2000 ml | 20-2000 ml | 2-2000 ml |
| **Maximum working pressure limitation** | 60 $cmH_2O$ | 60 $cmH_2O$ | 60 $cmH_2O$ |
| **PEEP setting** | 0-35 cmH2O<br>Neo: 3-25 cmH2O | 0-35 cmH2O | 0-35 cmH2O<br>Neo: 3-25 cmH2O |
| **Alarms and monitoring** | Yes | Yes | Yes |
| **Adjustable inspiration time total range** | 0.1-40 sec | 0.1-40 sec | 0.1-40 sec |
| **MRI department compatible?** | Yes | Yes | No |
| **Differences in technological characteristics** | - MR conditionality | - MR conditionality | - MR unsafe |
| | - Included Gaussmeter | - Included Gaussmeter | - No Gaussmeter included |
| | - Embedded system type: EM10A | - Embedded system type: EM01A | - Embedded system type: EM10A |
| | - Internal flow sensor with the ability to detect reflow | - Internal flow sensor without the ability to detect reflow | - Internal flow sensor with the ability to detect reflow |
| | - Expiratory valve recognition | - No expiratory valve recognition | - Expiratory valve recognition |
| | - Flashing alarm lamp | - Alarm lamp not flashing, only illuminated | - Flashing alarm lamp |
| | - Batteries with prolonged operating time | - Batteries without prolonged operating time | - Batteries with prolonged operating time |

Hamilton Medical has demonstrated the modified HAMILTON-MR1 ventilator to be substantial equivalent to currently marketed predicate devices that have been previously cleared by FDA.

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-MR1 operates as intended.

In particular, testing demonstrated that the HAMILTON-MR1 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 (2007): 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

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-MR1, 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 biocompatible materials or materials already used in earlier 510(k)s are introduced with this 510(k), Hamilton Medical did not conduct any additional testing.

The MRI environment test RF-Noise was redone to verify, that the modified device does not generate artifacts in the magnetic resonance image.

The system test magnetic immunity was redone to verify that the modified HAMILTON-MR1 is not negatively influenced by the magnetic field of a magnetic resonance imaging tomograph.

## VIII. CONCLUSION

The results of verification, validation, and testing activities demonstrate that the modified

HAMILTON-MR1 ventilator is as safe and as effective as the legally marketed devices identified herein.