HAMILTON MEDICAL

HAMILTON·G5

510(k) SUMMARY

SUBMITTER:	HAMILTON MEDICAL AG Via Crusch 8 Bonaduz, 7402 SWITZERLAND OCT 09 2013
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ESTABLISHMENT REGISTRATION NUMBER:	3001421318
PREPARATION DATE:	September 4th, 2013
TRADE NAME:	HAMILTON-G5
CLASSIFICATION NAME:	CLASS II Ventilator, Continuous (CBK) CLASS II Oximeter (DQA)
REGULATION NUMBER & PRODUCT CODE	21 CFR 868.5895 (CBK) 21 CFR 870.2700 (DQA)
PREDICATE DEVICE: (PRIMARY)	HAMILTON-G5 (K103803)
PREDICATE DEVICE: (SECONDARY)	MAQUET Servo-i (K073179) For the Volume-Support mode MASIMO RAINBOW SET RADICAL PULSE CO-OXIMETER (K100428) Nihon Kohden SpO_2 OXIMETER, PROBES, AND ACCESSORIES (K974292, K011918, K032749, K043517)

K131774

DEVICE DESCRIPTION

The HAMILTON-G5 is an electronically controlled pneumatic intensive care ventilator ventilation system. It uses oxygen and air or heliox to ventilate adults, pediatrics, infants, and neonates. It is powered by AC, and with battery backup in order to protect against power failure or unstable power and to facilitate intra-hospital transport. The HAMILTON-G5's pneumatics deliver gas -- while its electrical systems controls pneumatics, monitors alarms and distributes power. The user interface consists of a LCD-display with touch screen, keys, and a press-and- turn knob.

The HAMILTON-G5's new software version 2.30, includes a pulse oximetry function for continuous, non-invasive oxygen saturation monitoring (SpO_2).

Volume targeting in the HAMILTON-G5 is now supported by a new ventilation mode, called the Volume Support mode (VS). It is a flow-cycled, volume targeted, and pressure-regulated mode.

The Volume Support (VS) mode is designed for spontaneously breathing patients. It provides support to patient-initiated breaths so as to deliver the desired tidal volume (V_T), at a level appropriate to the patient's efforts. This mode allows the ventilator to change the support in response to changing patient conditions and inspiratory effort levels. To achieve this volume, the device decreases support when the patient's breathing activity increases or, conversely, increases support when the patient's inspiratory effort decreases.

INTENDED USE

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 healthcare 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.

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

The indication-of-use statement for the proposed HAMILTON-G5 ventilator is the same as the predicate HAMILTON-G5. In addition, the technological characteristics and performance specifications of the proposed HAMILTON-G5 ventilator are substantially equivalent to those of the predicate devices.

The new pulse oximetry function uses previously cleared devices, like the Masimo Rainbow Set Radical Pulse co-oximeter & accessories, as well as the Nihon Kohden SpO_2 oximeter & accessories. The new Volume Support mode in the HAMILTON-G5 is substantially equivalent to the MAQUET Servo-i's Volume Support mode.

HAMILTON MEDICAL has demonstrated the modified HAMILTON-G5 ventilator to be substantially equivalent. The proposed ventilator is considered to be substantially equivalent to the currently marketed predicate devices, which have been previously cleared by FDA.

COMPARISON TABLE BETWEEN PROPOSED AND PREDICATE DEVICE

The following table compares the proposed HAMILTON-G5 with its predicate device, the HAMILTON-G5 (K103803).

	Proposed device: HAMILTON-G5	**Predicate device: HAMILTON-G5 (K103803)**	**Equivalence**
Software version	SW 2.30	SW 2.0	Substantially Equivalent
Ventilator modes	(S)CMV, SIMV, SPONT, ASV, P-CMV, P-SIMV, APVcmv, APVsimv, DuoPAP, APRV, NIV, NIV-ST, nCPAP-PS, **Volume Support**	(S)CMV, SIMV, SPONT, ASV, P-CMV, P-SIMV, APVcmv, APVsimv, DuoPAP, APRV, NIV, NIV-ST, nCPAP-PS	Substantially Equivalent. The Volume Support mode is new in the proposed HAMILTON-G5
Pulse Oximetry	Yes.	No	N/A The proposed HAMILTON-G5 Includes both the Masimo (K100428) and Nihon Kohden Pulse Oximetry (K974292, K011918, K032749, K043517)

	Proposed device: HAMILTON-G5	Predicate device: HAMILTON-G5 (K103803)	Equivalence
Indications of Use	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.	The HAMILTON-GS 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 healthcare professionals provide patient care. The HAMILTON-GS ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician. The HAMILTON-GS 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. In the USA, federal law restricts this device to sale by or on the order of a physician.	Substantially Equivalent
Operation environmental requirements	•5 to 40 °C (41 to 104 °F) •10 to 95%, non-condensing •1013 to 600 hPa	•5 to 40 °C (41 to 104 °F) •10 to 95%, non-condensing •1013 to 600 hPa	Equivalent
Input Power	AC: 100 to 240 V, 50/60 Hz	AC: 100 to 240 V, 50/60 Hz	Equivalent
Power Consumption	50 VA typical	50 VA typical	Equivalent

	Proposed device: HAMILTON-G5	Predicate device: HAMILTON-G5 (K103803)	Equivalence
Battery	One batteries, Li-ion, sealed, maintenance-free	One batteries, Li-ion, sealed, maintenance-free	Equivalent
Battery operating time (typical)	2 hours	2 hours	Equivalent
Safety features	• Apnea backup ventilation • Automatic self-tests • Alarms (operator-adjustable / non-adjustable) • Alarm backup buzzer • External flow sensor failure mode • Safety mode in case of technical failures • Air inlet HEPA filter monitoring • Monitored fan Event log	• Apnea backup ventilation • Automatic self-tests • Alarms (operator-adjustable / non-adjustable) • Alarm backup buzzer • External flow sensor failure mode • Safety mode in case of technical failures • Air inlet HEPA filter monitoring • Monitored fan Event log	Equivalent
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.	Equivalent
Maximum working pressure limitation	60 cmH_20	60 cmH20	Equivalent
Maximum inspiratory flow	210 L/min	210 L/min	Equivalent

NON-CLINICAL PERFORMANCE TESTS

Safety testing of the HAMILTON-G5, with the new options, was conducted and shows that the device is substantially equivalent to the predicate devices for its intended use. The new Volume Support mode was further subjected to waveform performance testing, as described by the standard ASTM F1100-90. The data provided from these tests were shown to be substantially equivalent to a legally marketed device.

Verification and Validation testing also demonstrated that the SpO_2 and pulse rate values, calculated by the OEM system, are not corrupted during communication to the HAMILTON-G5 host device. No modifications were made to the previously cleared oximeter systems. The results of the software verification and validation testing demonstrate that all specified requirements have been implemented correctly and completely.

	Draft Reviewer Guidance for Ventilators.1995
IEC 60601-1	General Requirements for Safety
IEC 60601-1-2	Electromagnetic Compatibility
IEC 60601-2-12	Critical Care Ventilators
IEC 60601-2-49	Essential performance of multi-function monitoring equipment.

CONCLUSION

The results of verification, validation, and testing activities demonstrate that the modified HAMILTON-G5 ventilator is substantially equivalent to the legally marketed 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 20993-0002

October 9, 2013

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

Re: K131774
Trade/Device Name: Hamilton-G5
Regulation Number: 21 CFR 868.5895
Regulation Name: Ventilator, Continuous
Regulatory Class: II
Product Code: CBK, DQA
Dated: September 5, 2013
Received: September 9, 2013

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 contact 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. 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,

Kwame Ulmer, M.S.
Acting Division 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: **K131774**

Device Name: HAMILTON-G5

Indication for 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)

Anya C. Harry -S

Digitally signed by Anya C. Harry -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anya C. Harry -S, 0.9.2342.19200300.100.1.1=0011315590
Date: 2013.10.09 15:28:27 -04'00'