K071194

HAMILTON MEDICAL
MAKING TECHNOLOGY SERVE MANKIND

OCT 18 2007

510(k) Summary

510(k) OWNER:	HAMILTON MEDICAL AG Via Crusch 8 CH-7402 Bonaduz Switzerland
CONTACT PERSON:	Joerg Schneider Phone: +41 81 660 64 79 Fax: +41 81 660 60 20 e-mail: jschneider@hamilton-medical.ch
PREPARATION DATE:	September 26, 2007
TRADE NAME:	RAPHAEL Color^{ASV}
COMMON NAME:	Continuous Ventilator
CLASSIFICATION NAME:	Ventilator, Continuous, Facility Use (21 CFR 868.5895, Product Code CBK)
REASON FOR THIS 510(K) SUBMISSION:	The RAPHAEL Color^{ASV} is a software modified version of the legally marketed device RAPHAEL Color (K052863)
LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCE IS BEING CLAIMED:	HAMILTON RAPHAEL Color 510(k) Number: K052863
	HAMILTON GALILEO Gold^{ASV} 510(k) Number: K061090

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DEVICE DESCRIPTION

The RAPHAEL Color^{ASV} is a software modified version of the legally marketed device RAPHAEL Color (K052863).

The RAPHAEL Color^{ASV} is a full-functioned intensive care ventilator. It can ventilate adult and pediatric patients weighing between 5 and 200 kg. The RAPHAEL Color^{ASV} offers a full spectrum of modalities, from the conventional to the new included Adaptive Support Ventilation, ASV.

ASV is designed to maintain at least the minute ventilation set by the clinician. ASV does this without exceeding a preset plateau pressure. ASV provides full ventilation in apnea or low-drive conditions, and then automatically returns control to the patient as spontaneous ventilation begins. ASV works automatically by continuous repetition of 3 steps:

1. Assess the patient breath-by-breath.
2. Calculate an optimal breath pattern based on the minimal work of breathing method by Otis (J Appl Physiol 1950: 592-607).
3. Approach the target by automatically adjusting mandatory rate and inspiratory pressure.

INTENDED USE

The RAPHAEL Color^{ASV} ventilator is intended to provide positive pressure ventilatory support in intensive care units.
The ventilator is intended for intensive care ventilation of adult and pediatric patients weighing between 5 and 200 kg.
The device is intended for use by properly trained personnel under the direct supervision of a licensed physician.
The RAPHAEL Color^{ASV} ventilator is intended for use at the bedside and for transport within a hospital or hospital-type facility, provided compressed air 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.
In the USA, federal law restricts this device to sale by or on the order of a physician.

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

The indication statements for the RAPHAEL Color^{ASV} ventilator are comparable to those for the predicate devices.

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All technological characteristics and performance specifications of the RAPHAEL Color^{ASV} ventilator are equivalent to those of the predicate device RAPHAEL Color (K052863), except for the new added ASV mode.
The ASV mode is comparable with the ASV mode of the predicate device HAMILTON GALILEO Gold^{ASV} (K061090).

SUMMARY OF NON-CLINICAL PERFORMANCE TESTS

The performance/qualification testing of the new added feature ASV has been done on modular, integration and system level. There were no performance deviations observed or documented during testing.
The ventilator performance has been further evaluated in accordance to the ASTM Standard F1100-90. No new question rose regarding safety and effectiveness of the complete instrument and its new feature.
As the implementation of the new software feature does not include any new hardware, certain tests could be omitted. However, the impact of the new software on the microcomputer system was tested and documented. No performance deviations were observed or documented during testing.

CONCLUSION

The ventilator RAPHAEL Color^{ASV} is, inclusive the new added ASV mode, substantially equivalent in safety and effectiveness to the HAMILTON RAPHAEL Color (K052863) and the HAMILTON GALILEO Gold^{ASV} ventilators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 18 2007

Mr. Joerg Schneider
Quality Engineer, R & D
Hamilton Medical AG
Via Crusch 8
CH-7402 Bonaduz
SWITZERLAND

Re: K071194
Trade/Device Name: RAPHAEL Color ASV
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: October 2, 2007
Received: October 5, 2007

Dear Mr. Schneider:

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.

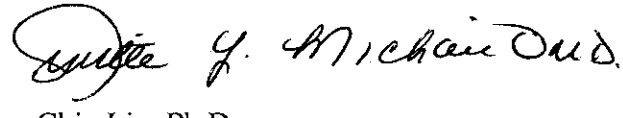
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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: K071194

Device Name: RAPHAEL Color^{ASV}

Indication for Use: The RAPHAEL Color^{ASV} ventilator is a continuous ventilator designed for ventilation of adult and pediatric patients weighing between 5 and 200 kg. The RAPHAEL Color^{ASV} ventilator is intended for use by properly trained personnel under direct supervision of a licensed physician. The RAPHAEL Color^{ASV} is intended for use in a hospital or hospital-type facility, including use at a patient bedside or for intra-facility transport, provided compressed gas is supplied.

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)

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

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