SUMMARY

JAN 6 2006

K052863

APPLICANTS NAME AND ADDRESS :	Hamilton Medical AG Via Crusch 8 CH-7402 Bonaduz Switzerland Establishment Registration 3001421318
OFFICIAL CORRESPONDENT:	Curdin Danuser HAMILTON MEDICAL AG Via Nova CH-7403 Rhaezuens Switzerland Phone: +41 81 660 60 10 Fax: +41 81 660 60 20 e-mail: cdanuser@hamilton-medical.ch
SUBMISSION CORRESPONDENT:	same as Official Correspondent
COMMON NAME:	Continuous Ventilator
PROPRIETARY NAME:	RAPHAEL Color
PURPOSE OF SUBMISSION:	New features for existing, legally marketed instrument in the US (K022679)
CLASSIFICATION:	Name: Ventilator, Continuous (per 21 CFR 868.5895) Panel: Anesthesiology Code: CBK
REGULATORY STATUS:	1. Current Device Class: Class 2 2. Performance Standards and Special Controls: None Exist

PREDICATE DEVICE IDENTIFICATION:

Legally marketed device to which equivalence is being claimed

Predicate Device	*Manufacturer*	*510(k) number(s)*	*Classification*
NIV mode and TRC feature			
GALILEO Gold	HAMILTON MEDICAL AG	K982910, K001686, K040574	Ventilator, Continuous, Facility Use per 21 CFR 868.5895

DEVICE DESCRIPTION

The RAPHAEL ventilator is a legally marketed intensive care ventilator (K022679). The two modifications included in this application are purely software-related and do not change the hardware of the RAPHAEL ventilator.

This application is for the following options to the RAPHAEL Color:

- The **NIV** (Non-Invasive Ventilation) **mode** is designed to facilitate ventilation assistance in a non-invasive way (e.g. a facial, a nasal mask or a mouth piece) between the ventilator and the patient's airway.

- **TRC** (Tube Resistance Compensation) is a feature to minimize the patient's work of breathing to overcome the additional airway resistance due to the presence of an ET-tube or a tracheotomy tube.

INTENDED USE
The RAPHAEL Color ventilator is a continuous ventilator in intensive care units.

INTENDED OPERATOR
The RAPHAEL Color ventilator is intended for use by properly trained personnel under the direct supervision of a licensed physician.

INTENDED PATIENT POPULATION
The RAPHAEL Color is intended for ventilation of adult. pediatric, and infant patients weighing between 5 and 200 kg.

INTENDED USE ENVIRONMENT
The RAPHAEL Color ventilator is intended for use in a hospital or hospital-type facility, including use at a patient bedside or for intrafacility transport, provided compressed air is supplied.
The RAPHAEL Color is not to be used in the presence of flammable anesthetic agents or other ignition sources.
The RAPHAEL Color is not to be used in an environment with magnetic resonance imaging (MRI) equipment.

SUBSTANTIAL EQUIVALENCE
The NIV and TRC modes of the RAPHAEL Color are substantially equivalent to the NIV and TRC modes of the GALILEO Gold ventilator.

SUMMARY OF PERFORMANCE TESTS
The performance/qualification testing of the new added features of the RAPHAEL Color ventilator (NIV and TRC modes) has been done on modular, integration, and system test level. The modular and integration testing of the new software-based features have been successfully performed for each individual new mode. System tests were executed with a complete instrument, i.e. the new software together with the existing RAPHAEL Color hardware. As presented during the accompanying documentation, there were no performance deviations observed or documented during modular, integration, and system testing.

The ventilator performance has been further evaluated in accordance to the ASTM Standard F-1100-93. The graphical analysis of the waveforms shows that there are no new question raised regarding safety and effectiveness of the complete instrument and its new features.

As the implementation of the new software features in the RAPHAEL Color ventilator did not include any new hardware, certain tests could be omitted (e.g. the ASTM F-100 endurance testing, the EMC testing and the EN-60601-1 and EN 60601-2).

COMPARISON OF RAPHAEL NEW FEATURES TO PREDICATE DEVICES

The following tables compare the major technological performance characteristics of the new RAPHAEL Color features to its predicate device. There are no significant differences between the new RAPHAEL Color features and its predicate.

NIV MODE (Non Invasive Ventilation)

Function	NIV	NIV	Discussion of the differences
Product name	RAPHAEL Color	GALILEO Gold	---
Manufacturer	Hamilton Medical AG	Hamilton Medical AG	---
The 510(k) numbers	To be assigned	K982610, K001686, K040574	---
Underlying mode	Pressure support	Pressure support	No differences
Inspiration triggered by patient	Yes	Yes	No differences
Pressure-limited inspiration	Yes	Yes	No differences
Inspiration termination	Flow-cycled (first) Time-cycled (second)	Flow-cycled (first) Time-cycled (second)	No differences
Indicated patient population	For spontaneously breathing patients only	For spontaneously breathing patients only	No differences
Apnea ventilation	Yes	Yes	No differences

TRC (Tube Resistance Compensation)

Function	NIV	NIV	Discussion of the differences
Product name	RAPHAEL Color	GALILEO Gold	---
Manufacturer	Hamilton Medical AG	Hamilton Medical AG	---
The 510(k) number	To be assigned	K982610, K001686, K040574	---
To minimize additional WOB_{pt} caused by ET-tube or tracheostomy tube	Yes	Yes	No difference
Compensate the resistance from an ET-tube or a tracheostomy tube	Yes	Yes	No difference
Apply instantaneous opposite counter-force to offset the resistance	Yes	Yes	No difference
Compensation works in both inspiration and expiration phases	Yes	Yes	No difference
User must set up tube type, size and compensation intensity	Yes	Yes	No difference
Display on-line a calculated intra-tracheal pressure curve	Yes	Yes	No difference

CONCLUSION:

The tests executed and documented in this application indicate that the RAPHAEL Color including the two modifications meets its performance specifications, is substantially equivalent in terms of performance features and specifications of the predicate device referenced within this premarket 510(k) notification, and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 6 2006

Mr. Curdin Danuser
Official Correspondent
Hamilton Medical AG
Via Crusch 8
CH-7402 Bonaduz
SWITZERLAND

Re: K052863
Trade/Device Name: RAPHAEL Color
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: October 6, 2005
Received: October 12, 2005

Dear Mr. Danuser:

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) 276-0120. 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

510(k) Number (if known): __________

Device Name: RAPHAEL Color

Indications for Use: The RAPHAEL Color ventilator is a continuous ventilator designed for ventilation of adult, pediatric, and infant patients weighing between 5 and 200 kg. The RAPHAEL Color ventilator is intended for use by properly trained personnel under direct supervision of a licensed physician. The RAPHAEL Color 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)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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