K040574

OCT 27 2004

10 SUMMARY

APPLICANTS NAME AND ADDRESS	Hamilton Medical AG Via Nova CH-7403 Rhaezuens Switzerland
APPLICANTS CONTACT PERSON	Dr. Andreas Scheibe Phone: +41 81 660 60 10 Fax: +41 81 660 60 20 e-mail: ascheibe@hamilton-medical.ch
APPLICANTS CONTACT PERSON IN THE USA	Hamilton Medical Inc. Mr. David Thompson Post Office Box 30008 Reno, NV 89520 Phone: 775-858-3200, Extension 349 Fax: 775-856-5621 e-mail: thompson@hammed1.com Establishment Registration 2937708
DATE THE SUMMARY WAS PREPARED	
COMMON NAME	Continuous Ventilator
PROPRIETARY NAME	GALILEO Gold
PURPOSE OF SUBMISSION	New features for existing, legally marketed instrument in the US (K982910, K001686)
CLASSIFICATION	Name: Ventilator, Continuous (per 21 CFR 868.5895) Panel: Anesthesiology Code: CBK
REGULATORY STATUS	1. Current Device Class: Class 2 2. Performance Standards & Special Controls: None Exist

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PREDICATE DEVICE IDENTIFICATION

Legally marketed devices to which equivalence is being claimed

Predicate Device	*Manufacturer*	*510(k) number(s)*	*Classification*
DuoPAP and APRV modes			
RAPHAEL	HAMILTON Medical AG	K02267	Ventilator, Continuous, Facility Use per 21 CFR 868.5895
Puritan Bennett 840	Nellcor Puritan-Bennett	K984535, K001646	Ventilator, Continuous, Facility Use per 21 CFR 868.5895
NIV mode			
Evita 4	Draeger Medizintechnik AG	K010093	Ventilator, Continuous, Facility Use per 21 CFR 868.5895
MMV$^+$ mode			
Siemens Servo^i	Siemens-Elema AB	K010925, K022132	Ventilator, Continuous, Facility Use per 21 CFR 868.5895
Siemens Servo 300A	Siemens-Elema AB	K970839	Ventilator, Continuous, Facility Use per 21 CFR 868.5895
Evita 4	Draeger Medizintechnik AG	K980642	Ventilator, Continuous, Facility Use per 21 CFR 868.5895
TRC feature			
Evita 4	Draeger Medizintechnik AG	K992608	Ventilator, Continuous, Facility Use per 21 CFR 868.5895

K944574

DEVICE DESCRIPTION

The Galileo ventilator is a legally marketed intensive care ventilator (K982910, K001686). The four modifications included in this application are purely software-related and do not change the hardware of the Galileo Gold ventilator.

This application is for the following options to the Galileo Gold ventilator:

- The **DuoPAP** (Duo Positive Airway Pressure ventilation) **and APRV** (Airway Pressure Release Ventilation) **ventilation modes** are two modes technically almost identical. In both modes, the ventilator alternates the airway pressure between two positive levels according to the preset controls. The ventilated patient can breathe at either pressure level. The spontaneous breaths are synchronized with the automatic switchover between the two pressure levels.

- 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.

- The **MMV$^+$** (Mandatory Minute Ventilation with Advanced Performance) **mode** is a pressure-controlled, minute volume-constant ventilation with controlled P_{sup} and ventilation rate. The patient pressure is controlled to PEEP + P_{sup} during the insufflation and to PEEP during the expiration. The patient target pressure is identical for the mandatory and for the spontaneous breaths. The mandatory ventilation rate and the inspiration time are set by the clinician. Depending on the patient's spontaneous breath rate, some mechanical breaths are added to achieve the mandatory rate.

- **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 GALILEO Gold is intended to provide positive pressure ventilatory support in intensive care units.

INTENDED OPERATOR

The GALILEO Gold is intended for use by properly trained personnel under the direct supervision of a licensed physician. In the US, federal laws restricts this device to sale by or on the order of a physician.

INTENDED PATIENT POPULATIONS

The GALILEO Gold is intended for intensive care ventilation of adults, pediatric and infant patients.

INTENDED USE ENVIRONMENT

The GALILEO Gold is intended for use at the bedside and for transport within a hospital or hospital-type facility, provided compressed gas is supplied.
The GALILEO Gold is not to be used in the presence of flammable anesthetic agents or other ignition sources.
The GALILEO Gold is not to be used in an environment with magnetic resonance imaging (MRI) equipment.

SUBSTANTIAL EQUIVALENCE

The DuoPAP and the APRV mode of the GALILEO Gold is substantially equivalent to the DuoPAP and APRV modes of the RAPHAEL ventilator and to the BiLevel mode of the Puritan-Bennett 840 ventilator system.
The NIV mode of the GALILEO Gold is substantially equivalent to NIV option of the Evita 4 ventilator.
The TRC feature of the GALILEO Gold is substantially equivalent to the ATC option of the Evita 4 ventilator.
The MMV+ mode of the GALILEO Gold is substantially equivalent to the MMV mode of the Evita 4 ventilator and to the Automode of the Servo 300A and Servo^i ventilators.

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SUMMARY OF PERFORMANCE TESTS

The performance/qualification testing of the new added Galileo Gold features (DuoPAP/APRV, NIV, TRC and MMV$^+$) has been done on modular, integration and system 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 Galileo Gold hardware. As presented within 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 F1100-93. The graphical analyses of the waveforms shows that there is 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 Galileo Gold instrument did not include any new hardware, certain tests could be omitted (e.g. the ASTM F-1100 endurance testing, the EMC testing and the EN-60601-1 and EN 60601-1-2). However, the impact of the new software on the microcomputer system (execution times of the different communication processes, reaction times and the overall load) were tested and documented. As presented within the accompanying documentation, there were no performance deviations observed or documented during the testing.

COMPARISON OF GALILEO GOLD NEW FEATURES TO PREDICATE DEVICES

The four following tables compare the major technological performance characteristics of the new Galileo Gold features to its predicate devices. There are no significant differences between the new Galileo Gold features and its predicates.

MAJOR FEATURE COMPARISON

DUOPAP & APRV (DUAL PRESSURE VENTILATION MODE)

Function	DuoPAP & APRV	BiLevel	DuoPAP & APRV	Discussion of the differences
Product name	Galileo Gold	PB 840	Raphael	---
Manufacturer	Hamilton Medical	Nellcor Puritan-Bennett	Hamilton Medical	---
The 510(K) number	To be assigned	K970460, K984535, K993071, K001646, K021573	K022679	---
Automatic and regular switchover between two pre-set pressure levels	Yes	Yes	Yes	No difference
The ventilated patient can breathe freely at either pressure level	Yes	Yes	Yes	No difference
The spontaneous breaths may be pressure-supported if desired	Yes	Yes	Yes	No difference
The "control breaths" are synchronized to the spontaneous breaths by the ventilated patients	Yes	Yes	Yes	No difference

NIV MODE (NON INVASIVE VENTILATION MODE)

Function	NIV	NIV option	Discussion of the differences
Product name	Galileo Gold	Evita	---
Manufacturer	Hamilton Medical	Draeger	---
The 510(k)	To be assigned	K961687, K980642, K992608, K010093	---
Underlying mode	Pressure support	Pressure support	No differences
How the inspiration is triggered	Patient-triggered	Patient-triggered	No differences
How the inspiration is limited	Pressure-limited	Pressure-limited	No differences
How the inspiration is terminated	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 possible?	Yes	Yes	No differences

TRC (TUBUS RESISTANCE COMPENSATION):

Function	TRC	ATC option	Discussion of differences
Product name	Galileo Gold	Evita 4	---
Manufacturer	Hamilton Medical	Draeger	---
510(k) number	To be assigned	K961687, K980642, K992608, K010093	---
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
Users must set up the tube type, size and compensation intensity	Yes	Yes	No difference
Display on-line a calculated intra-tracheal pressure curve	Yes	Yes	No difference

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MMV+ (MANDATORY MINUTE VENTILATION WITH ADVANCED PERFORMANCE)

Major feature of ventilation	MMV+	MMV	Automode	
Product name	Galileo Gold	Evita 4	Servo i and Servo 300 A	
Manufacturer	Hamilton Medical	Draeger	Siemens	
			PRVC	VS
User sets target minute ventilation	Yes	Yes	Yes	No
User sets target tidal volume	Yes	Yes	Yes	No
User sets target rate	Yes	Yes (only the minimum mandatory rate)	Yes	No
Regulated inspiratory pressure	Yes	No	Yes	Yes
Regulated respiratory rate	Yes	Yes	No	No
Assured minimum target minute ventilation	Yes	Yes	Yes	No
Switch between mandatory and spontaneous breaths	Yes	No	Yes	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2004

Mr. J. David Thompson
General Manager
Hamilton Medical, Incorporated
P.O. Box 30008
Reno, Nevada 89520

Re: K040574
Trade/Device Name: Galileo Gold Ventilator
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: September 30, 2004
Received: October 1, 2004

Dear Mr. Thompson:

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.

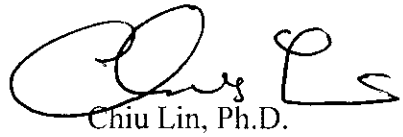
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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/dsma/dsmamain.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: **K 040574**

Device Name: **Galileo Gold ventilator**

Indication for Use: The Galileo Gold ventilator is intended to provide positive pressure ventilatory support to Adults, Pediatrics and Infants. The device is intended for use in the hospital and institutional environment where healthcare professionals provide patient care, including use as a patient bedside or for intra-facility transport, provided compressed gas is supplied. The device is not intended for transportation outside the hospital or for use in the home environment.

Prescription Use __X__ (Per 21 CFR 801 Subpart D) OR Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE–CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Courtesy Oi for AAG

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

510(k) Number: K040574