K080181

HAMILTON MEDICAL

JUN 2 4 2008

510(k) Summary

SUBMITTER:	HAMILTON MEDICAL AG Via Crusch 8 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:	April 08, 2008
TRADE NAME:	GALILEO Gold
COMMON NAME:	Continuous Ventilator
CLASSIFICATION NAME:	Ventilator, Continuous, Facility Use (21 CFR 868.5895, Product Code CBK)
LEGALLY MARKETED DEVICES TO WHICH EQUIVALENCE IS BEING CLAIMED:	HAMILTON GALILEO Gold^{ASV} 510(k) Number: K061090
	MAQUET Servo-i 510(k) Number: K041223
	GE Datex-Ohmeda Engström Carestation 510(k) Number: K062710

HAMILTON MEDICAL

DEVICE DESCRIPTION

The GALILEO Gold is an electronically controlled pneumatic intensive care ventilator ventilation system. It uses oxygen and air to ventilate adult, pediatric, infant, and neonatal patients. It is powered by ac with battery backup to protect against power failure or unstable power and to facilitate intrahospital transport.
The GALILEO Gold's pneumatics deliver gas, and its electrical systems control pneumatics, monitor alarms, and distribute power. The user interface consists of a LCD-display with touch screen, keys, and a press-and-turn knob. The GALILEO Gold provides audible and visual patient- and ventilator-related alarms.

INTENDED USE

The GALILEO Gold ventilator is intended to provide positive pressure ventilatory support to adult, pediatric, infant, and neonatal patients.
The device is intended for use in the hospital and institutional environment where healthcare professionals provide patient care, including use at the patient bedside and for intrafacility transport, provided compressed gas is supplied.
The GALILEO Gold ventilator 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.

INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS OF THE NEW DEVICE COMPARED TO THE PREDICATE DEVICES

The technological characteristics of the previous GALILEO Gold^{ASV} ventilator have not been changed for the new device GALILEO Gold. The expanding of the intended use to neonatal patients does not result in the use of new technological characteristics.
The GALILEO Gold's indication statements and its neonate ventilation characteristics are substantially equivalent to those of the predicate devices *Servo-i* and *Engström Carestation*.

NONCLINICAL PERFORMANCE TEST DATA SUBMITTED

The ventilator was subject to wave-form performance testing as described in the standard F1100 - 90. The data provided from these tests, were shown to be substantially equivalent to a legally marketed device.

CONCLUSION

HAMILTON MEDICAL has demonstrated the GALILEO Gold ventilator to be safe and effective when used as labeled.
This device is considered to be substantially equivalent to currently marketed predicate devices and the expanding of the intended patient population to neonates does not raise new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 24 2008

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

Re: K080181
Trade/Device Name: GALILEO Gold
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: CBK
Dated: June 4, 2008
Received: June 9, 2008

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,

Susan Runner

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: K080181

Device Name: GALILEO Gold

Indication for Use: The GALILEO Gold ventilator is intended to provide positive pressure ventilatory support to adult, pediatric, infant, and neonatal patients.
The device is intended for use in the hospital and institutional environment where healthcare professionals provide patient care, including use at the patient bedside and for intrafacility 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___ (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

510(k) Number: K080181