5. 510(K) SUMMARY

MAY 1 9 2000

K994188

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. § 807.92.

1. The submitter of this premarket notification is :

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The summary was prepared on December 6, 1999.

2. The name of this device is the Agilent Technologies M1026A Anesthetic Gas Monitor Option C05 for use with the Agilent Technologies Model M1166A Component Monitoring System (CMS) and Viridia 24 Agilent Technologies Model 1204A. The common name is the Agilent Technologies Anesthesia Gas Monitor. Classification names are as follows:

Regulation number	**Classification name**
868.1400	Carbon dioxide gas analyzer
868.1500	Enflurane gas analyzer
868.1620	Halothane gas analyzer
868.1700	Nitrous oxide gas analyzer
868.1720	Oxygen gas analyzer
868.2375	Breathing frequency monitor
Unclassified	Desflurane gas analyzer
Unclassified	Isoflurane gas analyzer
Unclassified	Sevoflurane gas analyzer

The unclassified gas analyzers for desflurane, isoflurane and sevoflurane are similar to the gases classified under 868.1500, enflurane, and 868.1620, halothane. Analysis of these gases has been cleared under the original M1026A AGM 510(k) no. K951127 and K982619

3. The above device is substantially equivalent to the Agilent Technologies M1026A marketed pursuant to K951127 and K982619.

4. The above device operates with Agilent Technologies Anesthesia Component Monitoring System (ACMS) and the Viridia 24 Agilent Technologies Model 1204A through a digital interface (RS232). The monitoring system is known as the Model M1166A Component Monitoring System (CMS). When coupled with the above ACMS, the device will measure and display respiratory gases and anesthetic agents of ventilated patients. The device will signal physiological alarms and document deviations when preset limits are exceeded. An INOP ("inoperative") alarm is triggered and a message is displayed in the event of malfunction, lack of detectable breath, power disconnects, and other inoperative states.

5. The device has the same intended use as the legally marketed predicate device. When connected to the ACMS, it is the intended for measuring the airway gases of ventilated patients within the anesthesia environment during the induction and maintenance of, and emergence from, anesthesia.

6. The technological characteristics are the same or similar to those found with the predicate device. Using the Andros Inc. Model 4700 MGM Multi Gas Module, the concentration of respiratory and anesthetic gases is calculated for patients under anesthesia by non-dispersive infrared analysis. Fast O2 measurement is done using the Servomex PM1111 D/E paramagnetic transducer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 9 2000

Mr. Herbert van Dyk
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Healthcare Solution Group
Herrenberger Straße 130 - 71034 Böblingen
Germany

Re: K994188
Anesthesia Gas Monitor M1026A
Regulatory Class: II (two)
Product Code: CBQ, CBS
Dated: April 18, 2000
Received: April 20, 2000

Dear Mr. Van Dyk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page __ of ___

510(k) Number (if known): K994188

Device Name: Agilent Technologies M1026A Anesthesia Gas Monitor

Indications for Use:

The M1026A Anesthesia gas Module is intended to measure and monitor anesthesia gas contents in the ventilation circuitry of a patient and to provide this data to health care professionals in form readings, waves and alarms, via the Component Monitoring System, for the support of clinical decision making.

The device is indicated for use in health care facilities by health care professionals whenever there is a need for adult, pediatric and neonate patient anesthesia gas monitoring.

MRI Compatibility Statement: The M1026A is not intended for use in a MRI magnetic field

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

Concurence of CDRH, Office of Device Evaulation (ODE)

for Mark N Melkerson

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K994188

(Optional Format 3-10-98)

(Posted July 1, 1998)

✓ prescription use