K972962

3M Health Care
Cardiovascular Systems
CDI™ Products

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NOV - 6 1997

3M

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. The assigned 510(k) number is _____.

Submitter's Name:	3M Health Care
Submitter's Address:	1311 Valencia Avenue, Tustin CA 92780
Contact Person:	Anne Buteyn
Phone Number:	(313)741-6338
FAX Number:	(313)663-5062
Summary Date:	August 8, 1997

Device Trade Name:
3M CDI Blood Parameter Monitoring System 500

Device Classification Name:
Cardiopulmonary bypass on-line blood gas monitor and cardiopulmonary bypass in-line blood gas sensor (21 CFR 870.4330)

Predicate Devices:

K890113	System 400 CDI Extracorporeal Blood Gas Monitoring System
K902654	System 100 CDI Hematocrit/Oxygen Saturation Monitoring System
K854357	Mallinckrodt Gem 6 Blood Gas/Electrolyte Monitor

Device Description:
The 3M CDI Blood Parameter Monitoring System 500 is an AC-powered (battery backup), microprocessor-based device used with disposable sensor elements for the purpose of monitoring arterial and/or venous pH, pCO_2, pO_2, potassium, saturation, hematocrit, and hemoglobin in the extracorporeal tubing circuit during partial or complete cardiopulmonary bypass.

The sensing element is introduced into the extracorporeal circuit by means of a heparin-coated sterile flow-through sensor for gas, potassium ion, and hydrogen ion measurement, and by means of a heparin-coated cuvette which allows measurement while maintaining a sterile path.

For pH, pCO_2, pO_2, and potassium measurement, a light is emitted from light emitting diodes (LED's) in the cable head to the sensors. Each sensor contains individual microsensors for the pH, pCO_2, pO_2, and potassium parameters. The microsensors contain fluorescent dyes which emit light in response to the stimulating light from the LED's. The intensity of the emitted light is dependent upon the concentration of O_2, CO_2, potassium ions or hydrogen ions coming in contact with the microsensors. The

intensity of the emitted light is then converted to a numerical value in mmHg, kilopascals, mEq/l, or pH units and displayed on the face of the monitor. For saturation, hematocrit and hemoglobin measurement, a light is emitted from LEDs in the probe to the cuvette and reflected back into the probe depending on the saturation of the blood and the hemoglobin present. The reflected light is then converted to a numerical value in saturation percentage, hematocrit percentage, or g/dl.

Indications for Use:
The 3M CDI Blood Parameter Monitoring System 500 is intended to provide continuous, on-line monitoring of the extracorporeal partial pressure of oxygen and carbon dioxide, pH, potassium, oxygen saturation, hematocrit, hemoglobin and temperature. In addition, calculated values of base excess, bicarbonate, oxygen saturation, and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37 ° C.

Technological Characteristics:
The 3M CDI System 500 is a combination of the technologies found in the 3M CDI System 400 and the 3M CDI System 100. The only differences between the 3M CDI Blood Parameter Monitoring System 500 and its predicate devices are:
- the use of an in-line shunt sensor only, rather than an in-line cell/sensor combination;
- the application of a covalently-bound heparin coating to the fluid path of the shunt sensor; and
- the addition of a microsensor for the measurement of potassium.

Nonclinical Performance:
The performance characteristics of the 3M CDI Blood Parameter Monitoring System 500 were exhaustively tested and compared with the performance characteristics of the currently marketed 3M CDI System 400 Blood Gas Monitoring System, the 3M CDI System 100 Hematocrit/Oxygen Saturation Monitoring System, and Mallinckrodt Gem 6 Blood Gas/Electrolyte Monitor. All new and existing performance characteristics of the 3M CDI Blood Parameter Monitoring System 500 have been validated.

Conclusions from Nonclinical Tests:
The 3M CDI Blood Parameter Monitoring System 500 performs as intended according to its performance specifications. The 3M CDI Blood Parameter Monitoring System 500 is substantially equivalent to its predicate devices.

2.2 Safety Literature Search

Although a safety literature search is not required for class II devices, one has been included below.

I certify that I have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported with cardiopulmonary bypass on-line blood gas monitors and cardiopulmonary bypass in line blood gas sensors within the past five years. I further certify that I am aware of the types of problems to which cardiopulmonary bypass on-line blood gas monitors and cardiopulmonary bypass in line blood gas sensors are susceptible and that the following list of safety and/or effectiveness problems about these devices is complete and accurate:

1) Occlusion of a cell or cuvette
2) Leakage of fluid from a cell or cuvette, or ingress of air emboli into a cell or cuvette
3) Loss of sterility

Below is a bibliography of the materials upon which the above summary is based:

1) Customer Complaint File, various dates, 3M CDI
2) U.S. Food and Drug Administration Recall Number Z 1084/1085-1. Initiated by 3M CDI on May 20, 1991.
3) U.S. Food and Drug Administration Recall Number Z 2628-2 through Z 2633-2. Initiated by 3M CDI on December 18, 1991
4) U.S. Food and Drug Administration Recall Numbers Z 635-2 through Z 645-2. Initiated by 3M CDI on February 2, 1991.
5) Medical Device Report M174488, filed 1/30/92 by 3M CDI.
6) Medical Device Report M174493, filed 2/4/92 by 3M CDI.
7) Medical Device Report M268836, filed 2/17/92 by 3M CDI.
8) Medical Device Report M268956, filed 2/19/92 by 3M CDI.
9) Medical Device Report M268957, filed 2/19/92 by 3M CDI.
10) Medical Device Report M255427, filed 2/13/92 by 3M CDI.
11) Medical Device Report M255429, filed 2/13/97 by 3M CDI.
12) Medical Device Report M174556, filed 2/12/92 by 3M CDI.
13) Medical Device Report M174629, filed 2/2/92 by 3M CDI.
14) Medical Device Report M174966, filed 4/16/92 by 3M CDI.
15) Medical Device Report M174942, filed 4/16/92 by 3M CDI.
16) Medical Device Report M174941, filed 4/16/92 by 3M CDI.
17) Medical Device Report M174943, filed 4/16/92 by 3M CDI.
18) Medical Device Report M174964, filed 4/16/92 by 3M CDI.
19) Medical Device Report M320347, filed 3/14/93 by 3M CDI.
20) Medical Device Report M377386, filed 3/26/93 by 3M CDI.
21) Medical Device Report M377387, filed 3/26/93 by 3M CDI.
22) Medical Device Report M377388, filed 3/26/93 by 3M CDI.

23) Medical Device Report M544290, filed 8/5/94 by 3M CDI.
24) Medical Device Report M800711, filed 4/17/95 by 3M CDI.
25) Medical Device Report M820946, filed 7/31/95 by 3M CDI.

Printed name of person required to submit 510(k): Anne M. Buteyn
Signature of person required to submit 510(k): Anne M Buteyn
Title of person submitting 510(k): Senior Professional Service Representative
Name of Company: 3M Health Care
Date: August 8, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Anne M. Buteyn
Senior Professional Service Representative
3M Health Care
Cardiovascular System
Sarns and CDI Products
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Tustin, California 92780

NOV - 6 1997

Re: K972962
3M CDI Blood Parameter Monitoring System 500
Regulatory Class: II (Two)
Product Code: DRY
Dated: August 8, 1997
Received: August 11, 1997

Dear Ms. Buteyn:

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 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/dsmamain.html."

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

870.4330 - DRY II - CPB On-Line Blood Gas Monitor

510(k) Number (if known): K972962

Device Name: 3M CDI Blood Parameter Monitoring System 500

Indications For Use:

The 3M CDI System 500 provides continuous, on-line monitoring of the extracorporeal partial pressure of oxygen and carbon dioxide, pH, potassium, oxygen saturation, hematocrit, hemoglobin and temperature. In addition, calculated values of base excess, bicarbonate, oxygen saturation, and oxygen consumption may also be provided. These parameters are displayed at either actual temperature or adjusted to 37° C. For documentation purposes, the system 500's integral printer provides a hard copy of displayed parameters.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K972962

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)