

K973472

DEC - 8 1997

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: Diana Rhea
Phone-Number: (714) 258-8001 X233
FAX Number: (714)258-0810
Summary Date:

Device Trade Name:
CDI 100 Extracorporeal Hematocrit/ Oxygen Saturation Monitoring System

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

Predicate Devices:

Product	510(k) Number	Clearance Date
CDI 100 Extracorporeal Hematocrit/Oxygen Saturation Monitoring System	K902654	11/5/90
PDR Thoracic Catheter, Atrium Medical (heparin coating only)	K912645	9/13/91

Device Description:

The 3M CDI H/S Cuvettes with Heparon Treatment are sterile, single-use medical devices. They are available in 1/4", 1/8", and 1/2" diameter sizes. Additionally, the 3M CDI H/S Cuvettes with Heparon Treatment have a covalently bound heparin coating.

Indications for Use:

The CDI 100 Extracorporeal Hematocrit/Oxygen Saturation Monitoring System is intended for use during cardiopulmonary bypass procedures when continuous monitoring of blood hematocrit, hemoglobin, and oxygen saturation is desired.

Technological Characteristics:

The only difference between the 3M CDI H/S Cuvettes with Heparon Treatment and the currently marketed 3M CDI H/S Cuvettes is the application of a covalently bound heparin coating to the fluid path of the devices. There are no dimensional changes to the cells and cuvettes due to the addition of the Heparon treatment.

Nonclinical Performance:

The performance characteristics of the 3M CDI H/S Cuvettes with Heparon Treatment were exhaustively tested and compared with the performance characteristics of the currently marketed 3M CDI H/S Cuvettes. All new and existing performance characteristics of the 3M CDI Heparin Coated H/S Cuvettes have been validated.

Clinical Performance:

Clinical testing was not performed on these devices.

Conclusions from Nonclinical Tests:

The 3M CDI H/S Cuvettes with Heparon Treatment perform as intended according to their performance specifications. The 3M CDI H/S Cuvettes with Heparon Treatment are substantially equivalent to their predicate devices.



Rockville MD 20857

Ms. Diana M. Rhea
Advanced Regulatory Affairs Coordinator
3M Health Care, Cardiovascular Systems
CDI Products
1311 Valencia Avenue
Tustin, California 92680

DEC - 8 1997

Re: K973472
CDI™ 100 Extracorporeal Hematocrit/Oxygen Saturation
Monitoring System
Regulatory Class: II (Two)
Product Code: DRY
Dated: September 11, 1997
Received: September 12, 1997

Dear Ms. Rhea:

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 (Pre-market 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 pre-market 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.

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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

510(k) Number (if known): K973472

Device Name: CDI H/S Cuvettes with Heparon Treatment

Indications For Use: These cuvettes are to be used with the CDI 100 Extracorporeal Hematocrit/Oxygen Saturation Monitoring System, which is intended for use during cardiopulmonary bypass procedures when continuous monitoring of blood hematocrit, hemoglobin, and oxygen saturation is desired.

(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 K973472

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)