

MAY 15 1998

### 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 K980732.

Submitter's Name: 3M Health Care  
Submitter's Address: 1311 Valencia Avenue, Tustin, CA 92780  
Contact Person: Diana Thorson  
Phone Number: (714) 258-8001 X233  
FAX Number: (714)258-0810  
Summary Date:

Device Trade Name:  
CDI 400 Extracorporeal Blood Gas 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 400 Extracorporeal Hematocrit/Oxygen Saturation Monitoring System	K890113	5/23/89
CDI 100 Extracorporeal Hematocrit/Oxygen Saturation Monitoring System	K902654	11/5/90

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

Indications for Use:  
The CDI 400 Extracorporeal Blood Gas Monitoring System is intended for use during cardiopulmonary bypass procedures when continuous monitoring of blood gases is desired.

Technological Characteristics:

This modification to the 3M CDI QUIK-CELLS includes the application of a covalently bound heparin coating to the fluid path of the device. In addition, the 3M CDI QUIK-CELLS with Heparin Treatment have a slightly thicker membrane. There are no other dimensional changes to the cells due to the addition of the Heparin Treatment.

Nonclinical Performance:

The performance characteristics of the 3M CDI QUIK-CELLS with Heparin Treatment were exhaustively tested and compared with the performance characteristics of the currently marketed 3M CDI QUIK-CELLS. All new and existing performance characteristics of the 3M CDI Heparin Coated QUIK-CELLS have been validated.

Clinical Performance:

Clinical testing was not performed on these devices.

Conclusions from Nonclinical Tests:

The 3M CDI QUIK-CELLS with Heparin Treatment perform as intended according to their performance specifications. The 3M CDI QUIK-CELLS with Heparin Treatment are substantially equivalent to their 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 the cell
- 2.) Leakage of fluid from the cell, or ingress of air emboli into the cell
- 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 Health Care, CDI Products.
- 2.) U.S. Food and Drug Administration Recall Number Z 1084/1085-1. Initiated by CDI, 3M Health Care on May 20, 1991.
- 3.) U.S. Food and Drug Administration Recall Number Z 2628-2 through Z2633-2. Initiated by CDI, 3M Health Care On December 18, 1991.
- 4.) U.S. Food and Drug Administration Recall Numbers Z-635-2 through Z-645-2. Initiated by CDI, 3M Health Care on February 2, 1992.
- 5.) Medical Device Report M174488, filed 1/30/92 by CDI, 3M Health Care.
- 6.) Medical Device Report M174493, filed 2/4/92 by CDI, 3M Health Care.
- 7.) Medical Device Report M268836, filed 2/17/92 by CDI, 3M Health Care.
- 8.) Medical Device Report M268956, filed 2/19/92 by CDI, 3M Health Care.
- 9.) Medical Device Report M268957, filed 2/19/92 by CDI, 3M Health Care.
- 10.) Medical Device Report M255427, filed 2/13/92 by CDI, 3M Health Care.
- 11.) Medical Device Report M255429, filed 2/13/92 by CDI, 3M Health Care.

- 12.) Medical Device Report M174556, filed 2/12/92 by CDI, 3M Health Care.
- 13.) Medical Device Report M174629, filed 2/2/92 by CDI, 3M Health Care.
- 14.) Medical Device Report M174966, filed 4/16/92 by CDI, 3M Health Care.
- 15.) Medical Device Report M174942, filed 4/16/92 by CDI, 3M Health Care.
- 16.) Medical Device Report M174941, filed 4/16/92 by CDI, 3M Health Care.
- 17.) Medical Device Report M174943, filed 4/16/92 by CDI, 3M Health Care.
- 18.) Medical Device Report M174964, filed 4/16/92 by CDI, 3M Health Care.
- 19.) Medical Device Report M320347, filed 3/14/93 by CDI, 3M Health Care.
- 20.) Medical Device Report M377386, filed 3/26/93 by CDI, 3M Health Care.
- 21.) Medical Device Report M377387, filed 3/26/93 by CDI, 3M Health Care.
- 22.) Medical Device Report M377388, filed 3/26/93 by CDI, 3M Health Care.
- 23.) Medical Device Report M544290, filed 8/5/94 by CDI, 3M Health Care.
- 24.) Medical Device Report M800711, filed 4/17/95 by 3M Health Care.
- 25.) Medical Device Report M820946, filed 7/31/95 by 3M Health Care.
- 26.) Medical Device Report 2023117-1997-00001, filed 3/14/97 by 3M Health Care.

Printed name of person required to submit 510(k): Diana M. Thorson

Signature of person required to submit 510(k): *Diana M. Thorson*

Title of person submitting 510(k): Advanced Regulatory Affairs Coordinator

Name of Company: 3M Health Care

Date: 2/24/98



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 15 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Diana M. Thorson  
Advanced Regulatory Affairs Coordinator  
3M Health Care, Cardiovascular Systems  
CDI Products  
1311 Valencia Avenue  
Tustin, CA 92780

Re: K980732  
3M CDI Quick-Cell with Heparin Treatment  
Regulatory Class: II (Two)  
Product Code: DRY  
Dated: February 24, 1998  
Received: February 25, 1998

Dear Ms. Thorson:

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 (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/dsma/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

510(k) Number (if known): K980732

Device Name: 3M CDI QUIK-CELLS With Heparin Treatment

Indications For Use: These cells are to be used with the CDI System 400 Extracorporeal Blood Gas Monitoring System, which is intended for use during cardiopulmonary bypass procedures when continuous monitoring of blood gases is desired.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Bette G. Campbell*

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K980732

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use     

(Optional Format 1-2-96)