NOV 23 1999

K983198

Section 10 : 510(k) Summary

This section satisfies the 510(k) summary as required by 21 CFR 807-92 ©.

Submitter

Miss Jan L Walters
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Short Street
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Date of Summary : August 1998

Device Name

Proprietary	:	TrendCare Calibrator
Common	:	Calibrator

Device Classification

Panel	:	Anaesthesiology Devices Panel
Classification	:	Accessory to a Class III device, indwelling pCO_2 partial pressure sensor
FDA CFR	:	868-1150
Description	:	Calibrator
Classification No.	:	~~75 JIS~~ 73 CCC

Statement of Substantial Equivalence

Diametrics Medical Ltd claims substantial equivalence to products which have received FDA clearance by the Premarket Notification process.

The TrendCare Calibrator is a duplication of the calibration function within the TrendCare Senior Monitor to provide a standalone calibration facility.

Device Description

The TrendCare Calibrator is a microprocessor-based device powered from the mains (line) supply. The device incorporates:

- A LCD display for user prompts.
- A series of LEDs for system status indication.
- Keys for selecting and initiating calibration.
- Calibration chamber.
- Connections to calibration gas cylinders.
- Location fixtures for the multiparameter sensors.

The calibration chamber is located on the front of the Calibrator unit, and is opened by pressing the latch to release the door.

The sensor is calibrated by connecting it to the PDM patient cable, placing the tonometer in the calibration chamber, closing the door and securing the introducer, and pressing the START CAL key.

A three point calibration of the sensor is performed by bubbling three precision mixtures of oxygen, carbon dioxide and nitrogen in sequence through the tonometer solution surrounding the sensor. These gases change the partial pressure of oxygen and carbon dioxide and the pH in the tonometer to defined values.

The calibration gases are contained in cylinders located at the base of the Calibrator. The cylinders are identical to the predicate device. Each cylinder contains a different precision mixture of gases. These gases are automatically passed in sequence through the tonometer when the calibration sequence is initiated.

Each of the cylinders contains sufficient gas for multiple calibrations. The cylinders are disposable, and should be discarded when empty (see the instructions on the cylinder labels).

Intended Use

The TrendCare Calibrator is an accessory for use with the TrendCare Monitors. Sensors and Patient Data Modules calibrated with the TrendCare Calibrator may be used with the TrendCare Satellite Monitor (TCM6000) or TrendCare Senior Monitor (TCM7000).

Technological Characteristics

- Mains powered
- Microprocessor controlled
- Digital display

Conclusion

The data presented above satisfies product accuracy claims and shows comparable results for both the TrendCare Calibrator and the TrendCare Senior Monitor.

The device under review is considered substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 23 1999

Miss Jan L. Walters
Diametrics Medical Ltd.
Short Street
High Wycombe
Bucks HP11 2QH
United Kingdom

Re: K983198
TrendCare Calibrator
Regulatory Class: III (three)
Product Code: 73 CCC
Dated: September 11, 1998
Received: September 11, 1998

Dear Miss Walters:

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,

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): K983198

Device Name: TRENDCARE CALIBRATOR

Indications For Use:

The TrendCare Calibrator is an accessory for use with the TrendCare Monitors. Sensors and Patient Data Modules calibrated with the TrendCare Calibrator may be used with the TrendCare Satellite Monitor (TCM6000) or TrendCare Senior Monitor (TCM7000)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Prescription Use ✓ 510(k) Number _____ OR _____ Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)