

9.0 510(k) SUMMARY: Corometrics TcpO₂/CO₂ Module

Prepared: 26 February 1998

[807.92(a)1] Contact Information

Richard J. Cehovsky
Regulatory Affairs Manager

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[807.92(a)2] Device Name and Classification

The proprietary name of the device to be introduced into interstate commerce is the Corometrics TcpO₂/CO₂ Module. Common name includes: TC Module and Solar TC Module.

Current classifications that apply to this device are: 21 CFR 868.2480, Cutaneous carbon dioxide monitor, Class II and 21 CFR 868.2500(a), Cutaneous oxygen monitor, Class II.

[807.92(a)3] Identification of Legally Marketed Equivalent Devices (Predicate Systems).

Predicate System	Manufacturer	K Number	Class
Cutaneous, Carbon Dioxide Sensor	Radiometer America Westlake, Ohio	K900333	II
Solar Series of Monitors	Marquette Medical Systems Milwaukee, WI	K954852	II

[807.92(a)4 & 807.92(a)5] Device Description & Intended Use

The Corometrics TcpO₂/CO₂ Module provided continuous monitoring of transcutaneous pO₂ and pCO₂ when used in conjunction with the Marquette Medical Systems' solar Monitor Series and the Tram-Rac 4A interface. The Solar monitor provides the display and control function for the TC Module.

510(k) SUMMARY (Continued): Corometrics TCpO₂/CO₂ Module

The Corometrics TcpO₂/CO₂ Module is intended for non-invasive monitoring of oxygen and/or carbon dioxide in neonates not under anesthesia. The device is intended for use in a hospital/clinical environment.

[807.92(a)6] Predicate Device Comparison of Technological Characteristics

TcpCO ₂ Monitoring Capability	Yes	No	Yes
TCpO ₂ Monitoring Capability	Yes	No	Yes
TcpCO ₂ User Interface and Display Capability	Yes	Yes	No
TCpO ₂ User Interface and Display Capability	Yes	Yes	No

[807.92(b)1, 807.92(b)2 & 807.92(b)3] Performance Standards per the Food, Drug Cosmetic Act

To date, the Food and Drug Administration have promulgated no performance standards relating to devices of this type.

[807.92(d)] Additional Information

The Corometrics TCpO₂/CO₂ Module has been extensively tested to meet its requirements and design.

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 1998

Mr. Richard J. Cehovsky
Corometrics Medical Systems, Inc.
61 Barnes Park Road North
P.O. Box 333
Wallingford, CT 06492-0333

Re: K980756
Corometrics Transcutaneous TCpO₂/pCO₂ Module
Regulatory Class: II (two)
Product Code: 73 LKD
Dated: August 6, 1998
Received: August 7, 1998

Dear Mr. Cehovsky:

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.

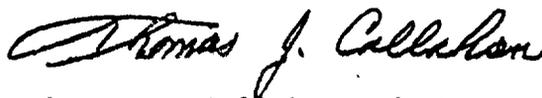
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 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.

Page 2 - Mr. Richard J. Cehovsky

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): K980756 *

Device Name: Corometrics TCpO₂/CO₂ Module

Indications for Use:

The Corometrics TCpO₂/CO₂ Module is used for non-invasive continuous monitoring of oxygen and/or carbon dioxide when used with the Marquette Medical System's Solar Monitor Series and TRAM-RAC 4A. It is indicated for use as a monitor of oxygen and/or carbon dioxide in neonates not under anesthesia.

* To be assigned by FDA upon receipt of 510(k) submission.

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

Concurrence if CDRH, Office of Device Evaluation (ODE)

Jonk Modro 11-3-98

Prescription Use
(Per 21 CFR 801.19)

OR

Over the Counter Use

Optional Format 1-2-96

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980756