DEC 21 2000

K984579

Optical Sensors Incorporated

510(k) Summary

Company Name:	Optical Sensors Incorporated
Device Name:	CapnoProbe A System
Contact:	Paulita LaPlante President and CEO Optical Sensors Incorporated 7615 Golden Triangle Drive Eden Prairie, MN 55344
Phone:	612-947-9595
Fax:	612-944-6022
Summary Date:	December 13, 2000
Trade Name:	CapnoProbe A System
Common Name:	Carbon Dioxide Gas Analyzer
Classification Name:	CFR 868-1400 73CCK Carbon Dioxide Gas Analyzer
Predicate Devices:	SensiCath Blood Gas Sensor – 510(k) K 951094 OpticalCAM Blood Gas Measurement System - 510(k) K963935 Datex-Engstrom Tonocap – 510(k) K 962638

1.0 Description of Device

The CapnoProbe A System provides a measurement of Sublingual pCO_2 (SL CO_2). The CapnoProbe A consists of a Disposable Sensor, Instrument, Fiber Optic Interconnect Cable and Calibration Fluid. The Disposable Sensor contains a fiber optic pCO_2 sensor and temperature sensor. The Disposable Sensor is placed under the tongue for a measurement of pCO_2 and temperature.

The Disposable Sensor connects to the fiber optic interconnect cable. The fiber optic interconnect cable connects to a software modified ABG Module.

The instrument is a software modified Optical CAM and ABG Module. The software-modified instruments measures SL CO_2 and temperature, displaying SL CO_2. The instrument is dedicated to the function as programmed by the software. The instruments are referred to as a CapnoProbe A Monitor and a CapnoProbe A Module. Prior to use the CapnoProbe A System with disposable pCO_2 sensor is calibrated with provided tonometered saline. The saline calibration fluid is the same as the predicate SensiCath System initialization fluid.

2.0 Intended use of Device

The CapnoProbe Sublingual Tonometer System is indicated for monitoring sublingual PCO2. It is indicated for use in hospital patients. This device is indicated for use by qualified medical personnel only.

3.0 Technological Characteristics

The technical characteristics of the CapnoProbe A System are measurement of pCO_2 by a fiber optic sensor. The fiber optic pCO_2 technical features of the CapnoProbe A System are equivalent to the predicate SensiCath Blood Gas Sensor and OpticalCAM Blood Gas Measurement System.

4.0 Data Summary

Laboratory and animal data are presented to establish and compare performance of the CapnoProbe A System to a predicate pCO_2 measurement system, the Tonocap TC-200. The bench data establishes performance of the CapnoProbe A System and Tonocap to controlled levels of tonometered saline. Both systems perform equally well under laboratory conditions.

The animal study demonstrates equivalence of pCO_2 measurement under the tongue, versus stomach mucosal tissue of test animals. Both systems tracked pCO_2 changes. The Pearson r Correlation Coefficient of the two CapnoProbe A Systems is higher than the Pearson r Correlation Coefficient of the two predicate Tonocap Systems.

A comparison of clinical data for the CapnoProbe A System and published Tonocap clinical data on volunteer and stable subjects indicates the CapnoProbe A System is as

repeatable as the predicate TonoCap System. A volunteer clinical study demonstrates repeatability of the CapnoProbe A System.

5.0 Conclusions

The data and information presented supports the conclusion the technology of the CapnoProbe A System is substantially equivalent to the noted predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

Ms. Paulita LaPlante
President & CEO
Optical Sensors Incorporated
7615 Golden Triangle Drive
Technology Park Five
Minneapolis, MN 55344

Re: K984579
Trade Name: CapnoProbe-A SL
Regulatory Class: II (two)
Product Code: 73 CCK, 73 CBR, 78 KNT
Dated: July 18, 2000
Received: July 20, 2000

Dear Ms. LaPlante:

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" (21CFR 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,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Sublingual Tonometer CO_2 Measurement System

Indications For Use:

The CapnoProbe Sublingual Tonometer System is indicated for monitoring sublingual PCO2. It is indicated for use in hospital patients. This device is indicated for use by qualified medical personnel only.

(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)

(Optional Format 3-10-98)

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