

DEC 21 2000

K 984579

## 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<sub>2</sub> (SL CO<sub>2</sub>). The CapnoProbe A consists of a Disposable Sensor, Instrument, Fiber Optic Interconnect Cable and Calibration Fluid. The Disposable Sensor contains a fiber optic pCO<sub>2</sub> sensor and temperature sensor. The Disposable Sensor is placed under the tongue for a measurement of pCO<sub>2</sub> 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 measure SL CO<sub>2</sub> and temperature, displaying SL CO<sub>2</sub>. 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<sub>2</sub> 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 PCO<sub>2</sub>. 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<sub>2</sub> by a fiber optic sensor. The fiber optic pCO<sub>2</sub> 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<sub>2</sub> 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<sub>2</sub> measurement under the tongue, versus stomach mucosal tissue of test animals. Both systems tracked pCO<sub>2</sub> 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.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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 (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

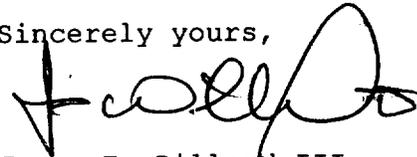
Page 2 - Ms. Paulita LaPlante

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<sub>2</sub> Measurement System

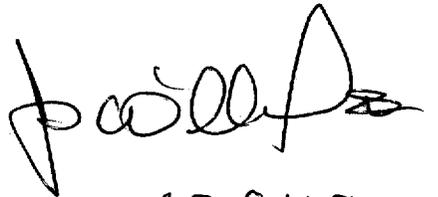
Indications For Use:

The CapnoProbe Sublingual Tonometer System is indicated for monitoring sublingual PCO<sub>2</sub>. 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)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

A handwritten signature in black ink, appearing to be "J. Wolf" or similar, written in a cursive style.

K984579