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OPTICAL SENSORS
INCORPORATED

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3.0 510(k) SUMMARY AND CERTIFICATION

A 510(k) Summary of Safety and Effectiveness, Class III Certification and Class III Summary of Safety and Effectiveness Problems is presented here.

3.1 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

This Summary of Safety and Effectiveness information is submitted in accordance with the requirements of SMDA 1990.

Re: 510(k) Pre-market Notification
SensiCath™ Arterial Blood Gas Sensor.

Submitted By: Optical Sensors Incorporated
7615 Golden Triangle Drive
Minneapolis, MN 55344

Date: 5/1/96

Contact Person: Denise Schottler,
Director Quality Assurance, Regulatory Affairs.

Device Name: SensiCath™ Arterial Blood Gas Sensor.

Common Name: Blood Gas Sensor.

Trade Name: SensiCath™ Arterial Blood Gas Sensor

Classification Name:

- 73 CCC 21 CFR 868.1150 Indwelling blood carbon dioxide partial (PCO_2) analyzer.
- 73 CBZ 21 CFR 868.1170 Indwelling blood hydrogen ion concentration (pH) analyzer.
- 73 CCE 21 CFR 868.1200 Indwelling blood oxygen partial pressure (PO_2) analyzer.

Predicate Device: 510(k) K95 1094
SensiCath™ Point-of-Care Blood Gas Monitor System

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3.1.1 DESCRIPTION OF THE DEVICE:

It is the intention of Optical Sensors Incorporated (OSI) and Marquette Electronics Incorporated (MEI) to introduce into commercial distribution a modification to the SensiCath Arterial Blood Gas Sensor. The modified sensor has a longer useful life and allows a greater number of ABG measurements. The modified sensor is substantially equivalent to the SensiCath Sensor presented in the SensiCath™ Point-of-Care Blood Gas Monitor System which received Food and Drug Administration (FDA) clearance to market, 510(k) K95 1094. The modified SensiCath Sensor operates with the SensiCath Point-of-Care Blood Gas Monitor System, just as the predicate SensiCath Sensor.

As with the predicate sensor, the modified SensiCath Sensor measures blood gas parameters of partial pressure of oxygen (PO_2), partial pressure of carbon dioxide (PCO_2) and the blood's hydrogen ion concentration, (pH). The modified SensiCath Sensor is manufactured and sterilized by Optical Sensors Incorporated, as is the predicate SensiCath Sensor.

3.1.2 STATEMENT OF INTENDED USE OF THE DEVICE

The modified SensiCath Sensor, when used as part of the Point-of-Care Blood gas Monitor System is intended to provide on-demand arterial blood gas monitoring in the operating room and at the bedside for critically ill patients requiring an arterial pressure monitoring line. The ABG information is available to the attending qualified medical professional on demand and within approximately 60 seconds of the time the sample cycle was initiated. The intended use of the modified SensiCath Sensor is the same as the predicate SensiCath Sensor.

3.1.3 COMPARISON

The modified SensiCath Sensor is equivalent to the predicate SensiCath Sensor in design, materials, clinical application and intended use. The modified SensiCath Sensor allows 144 hours of single patient use and a greater number of ABG measurements. The predicate SensiCath Sensor is limited to 72 hours of single patient use. The change in duration of use and number of ABG measurements result in labeling changes.

The affect of duration of use and number of ABG measurements has been evaluated. Performance data demonstrating the modified SensiCath Sensor meets performance specifications has been provided.

3.1.4 DISCUSSION OF PERFORMANCE DATA SUBMITTED IN SUPPORT OF THE SAFETY AND EFFICACY CLAIMS FOR THE MODIFIED SENSICATH SENSOR

Precision and accuracy tests were conducted on the modified SensiCath Sensor. Tonometered bovine blood was equilibrated with several gas mixtures. At different levels of carbon dioxide, pH and oxygen, measurements were taken using the sensor as part of the Point-of Care Blood Gas Monitor. The performance of the modified SensiCath Sensor meets the same performance specifications as the predicate SensiCath Sensor over 144 hours of use and 200 ABG measurements.

The results of this performance testing concludes there are no new safety or effectiveness issues with this labeling change. This information causes Optical Sensors Incorporated to conclude that no new or unanswered issues of safety or effectiveness are raised.