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4.0 510(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.

4.1 510(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
Olympus Critical Care Monitoring System.

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

Date: 9/30/96

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

Device Name: Olympus Critical Care Monitoring System.

Common Name: Blood Gas Monitor.

Trade Name: Olympus Critical Care Monitoring System.

Classification Name: Blood Gas Monitor.

Predicate Device: Point-of-Care Blood Gas Monitor System
510(k) K951094

Tram® System
510(k) K900598

4.1.1 DESCRIPTION OF THE DEVICE

It is the intention of Optical Sensors Incorporated (OSI) to introduce into commercial distribution an Olympus Critical Care Monitoring System (Olympus System). The Olympus System supports modules and sensors used in monitoring critical parameters at the patient bedside. The module and sensor referenced in this submission are the cleared-to-market arterial blood gas module (ABG Module) and SensiCath optical sensor unit (SensiCath Sensor). When the Olympus System includes an ABG Module and SensiCath Sensor, monitoring of arterial blood gas at the point-of-care is accomplished.

The ABG Module and SensiCath Sensor received Food and Drug Administration (FDA) clearance to market, 510(k) K951094. The predicate system is referred to as the Point-of-Care Arterial Blood Gas Monitoring System.

As in the predicate cleared-to-market system, the Olympus System measures blood parameters of partial pressure of oxygen (PO_2), partial pressure of carbon dioxide (PCO_2) and the hydrogen ion concentration, (pH). The Olympus System has three main components:

1. an optical arterial blood gas sensor, hereafter referred to as the SensiCath Sensor,
2. a module, the Arterial Blood Gas (ABG) Module, hereafter referred to as the ABG Module and,
3. an operator interface (display, control knob) with electrical and mechanical support for the ABG Module, hereafter referred to as the Olympus Monitor.

The SensiCath Sensor is manufactured by Optical Sensors Incorporated. The ABG Module is manufactured by Marquette Medical Systems and the Olympus Monitor is manufactured by SeaMED Corporation. The sponsor of this 510(k) pre-market notification is Optical Sensors Incorporated.

4.1.2 STATEMENT OF INTENDED USE OF THE DEVICE

The Olympus System is intended to provide on-demand arterial blood gas monitoring in the operating room and at the bedside for critically ill patients with a pre-existing 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.

4.1.3 COMPARISON

The Olympus System is designed to be used specifically with the ABG Module and SensiCath Sensor. The Olympus System can accommodate up to two modules simultaneously. At the present time, the only module supported by the Olympus System is the ABG Module. Only one ABG Module is used at a time. As other modules are developed, clearance-to-market will be submitted.

The Olympus System is designed to perform ABG measurements identical to the Point-of-Care Arterial Blood Gas Monitoring System. This system was cleared-to-market by 510(k) K951094.

The predicate system includes a Marquette Medical Systems Tram Monitoring System, (TramScope Monitor, Tram-Rac and Tram Module), ABG Module and SensiCath Sensor. When the Marquette Tram System includes an ABG Module and SensiCath Sensor, arterial blood gas monitoring can be performed. The Tram System was cleared-to-market by 510(k) K 900598.

4.1.4 DISCUSSION OF PERFORMANCE DATA SUBMITTED IN SUPPORT OF THE SAFETY AND EFFICACY CLAIMS

Precision and accuracy tests were conducted on the Olympus System over the range of ABG specifications. The Olympus System performance meets the same performance specifications as the predicate Point-of-Care Arterial Blood Gas Monitoring System.

The requirements for the Olympus System, with an ABG Module and SensiCath Sensor, require testing to the FDA "Reviewer's Guidance for Devices undergoing 510(k) review, November 1993", prior to commercial introduction.

No new questions of safety or effectiveness are raised.