

K963415

NOV 25 1996

SECTION 20

NON-CONFIDENTIAL SUMMARY OF SAFETY AND EFFECTIVENESS

Ventrex LLC
159 Gibraltar Road
Horsham, PA 19044

Tel: (215) 675-7714
Fax: (215) 675-7851

Official Contact: Ms. Mary Huegel
Regulatory Affairs Coordinator
Proprietary or Trade Name: VENTREX OXYGEN SENSOR
Common/Usual Name: Oxygen Sensor
Intended Device: Oxygen Sensor

Predicate Device:
Vascular Technology Oxygen Sensors K862113
Seatronics Oxygen Sensors K953351

Device Description:

The VENTREX line of oxygen sensors are medical devices which produce an electrical current which is directly proportional to the amount of oxygen contained in a gas mixture. Like any oxygen sensor, the VENTREX oxygen sensor electrical out-put must be interpreted by an electronic monitoring instrument. As is the case with all oxygen sensors, the VENTREX sensors will be used in the hospital, in physician offices, out-patient care centers, extended care facilities, homes, emergency medical services and patient transport.

VENTREX has identified the Vascular Technology (K862113) and Seatronics (K953351) line of oxygen sensors as legally marketed predicate devices.

The VENTREX line of oxygen sensors is not a modification or enhancement of the Vascular Technology and Seatronics line of oxygen sensors. Consequently, there is substantially no difference between the VENTREX line of oxygen sensors and the predicate devices. All of the oxygen sensors produce an electrical current which is directly proportional to the amount of oxygen present in a gas sample.

Each device has similar intended uses. The VENTREX line of oxygen sensors and predicate devices have similar clinical applications. Each is used to determine the amount (expressed as % O₂) of oxygen present in an atmosphere.

VENTREX has not been able to locate any national or international performance standards for Oxygen sensors. However, specific sections of ISO/DIS 7767 "Oxygen Monitors for Monitoring Patient Breathing Mixtures" apply to oxygen sensors. The VENTREX line of oxygen sensors has been tested and found to comply with the ISO/DIS 7767 standard. They also compare with the performance data published by the predicate manufacturers.

The VENTREX line of oxygen sensors will include the following sensor configurations:

1. V-O1 Oxygen Sensor
2. V-02 Oxygen Sensor
3. V-03 Oxygen Sensor
4. V-05 Oxygen Sensor
5. V-10 Oxygen Sensor
6. V-11 Oxygen Sensor
7. V-12 Oxygen Sensor
8. V-14 Oxygen Sensor
9. V-65 Oxygen Sensor

The VENTREX line of oxygen sensors is used in conjunction with electronic monitoring devices. The oxygen sensor is placed "in-line" so that it is exposed to the atmosphere which the patient will breath.

Conclusion:

The Vascular Technology, the Seatronics, and the VENTREX oxygen sensors are substantially equivalent in terms of configuration, materials, construction, and performance. They work on identical electro-chemical principles and are designed to provide the same signal range, proportional to the oxygen tension, to the same finished medical devices. Furthermore, the VENTREX cells have been tested and found to be compliant with the applicable requirements of ISO/DIS 7767, "Oxygen Monitors for Monitoring Patient Breathing Mixtures". For all of the reasons stated in this section, it is the position of VENTREX that the products included in this premarket notification are safe and effective.