Epic Medical Equipment Services
1800 10TH STREET, SUITE 300, PLANO, TEXAS 75074

510(k) Summary

Submitter Information:

Epic Medical Equipment Services, Inc.
1800 E. 10th Street, Suite 300
Plano, TX 75074

Contact:

Krista Oakes
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Telephone: (972) 801-9854
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Date Prepared:

June 30, 1999

Product Name:

Common Name: SpO2 Sensor (accessory to pulse oximeter)
Trade Name(s): SpO2 Wrap Sensor

Predicate Device:

This product is a modification to the Epic 100 Series SpO2 sensor marketed under 510(k) # K970098 and the Epic 200 Series Flexi-Site sensor marketed under K964055.

Description:

The SpO_2 Wrap Sensor is an electro-optical sensor which functions without skin penetration, electrical contact, or heat transfer. It is an accessory to compatible SpO_2 oximeters. The sensor uses optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter. The sensor contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector.

The LED's and photodiode are contained in a flexible, L-shaped housing that is positioned over the desired patient digit and secured in place with a fabric wrap.

The sensor cable is 3-12 feet in length and is terminated in DB-9 and Hypertronics style connectors.

Intended Use:

The SpO_2 Wrap Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring for patients weighing more than 30 kg.

Comparison to Predicate Device:

The SpO_2 Wrap Sensor uses the same theory and principle of operation as the predicate device. The Wrap Sensor differs from the predicate device in essentially two ways:

1) it uses a different housing/method of attachment to the patient (wrap design vs. clip design); and
2) it uses a smaller photodiode ($3mm^2$ vs. $8.23mm^2$)

The LED specifications, as well as the electrical/optical specifications of the photodiode, are identical to the predicate device.

Performance Data & Conclusions:

Changes to the predicate device do not affect those aspects of the device related to accuracy. Changes to the photodiode's mechanical size affects the device's ability to be recognized by the compatible oximeter. Simulated use bench testing was performed to verify oximeter compatibility with the smaller photodiode.

Other bench testing was performed to verify that the device meets the same standards as the predicate device, with regard to biocompatibility, EMC, safety, and pulse oximeter standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 22 1999

Ms. Krista Oakes
Epic Medical Equipment Services, Inc.
1800 10th Street, Suite 300
Plano, TX 75074

Re: K992211
SpO2 Wrap Sensor
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: October 1, 1999
Received: October 4, 1999

Dear Ms. Oakes:

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"(21 CFR 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 A Weiterhaus for,

Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications For Use

510(k) # K992211
Device Name: SpO_2 Wrap Sensor

Indications for Use:
The SpO_2 Wrap Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring for patients weighing more than 30 kg.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992211