4/9/99

K990082

10.0 510(k) Summary of Safety and Effectiveness Information

Date: 7 January, 1999

Establishment: Epic Medical Equipment Services
1800 10th Street Suite 300
Plano, TX 75074

Official Correspondent: Jeffrey Secunda
VP R&D
972-801-9854
972-801-9859 (fax)

Model Number /Name: E403-09 SpO_2 Finger Sensor

Classification Name: Oximeter – 74 DQA (CV)
21 CFR 820.2700 (Class II)

Predicate Devices: Epic Series E100 SpO_2 Finger Sensor (K970098)
Satlite Plus Pulse Oximeter (K905140)

Description of the Device:
The Epic Medical Equipment Services, Inc. E403-09 SpO_2 Finger Sensor is a reusable clip-on finger sensor with the optical components, protected in a hard plastic case. It functions without skin penetration, electrical contact, or heat transfer. This electro-optical sensor uses optical means to determine the light absorption of functional arterial hemoglobin by being connected between the patient and the oximeter. The E403-09 Finger 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 E403-09 is three feet in length and is terminated in a DB9 style connector as is the predicate sensor. The E403-09 is used with E710-09 10 foot cable which both extends the length of the E403-09 as well as adapts the DB9 connector to a Nicolay style connector which connects to the oximeter.

The E412-09 is equivalent to the E403-09 (3 foot) plus E710-09 (10 foot). The E412-09 is 12 feet long and terminates with a Nicolay style connector.

Statement of the Intended Use:
"Reusable sensor for continuous non-invasive functional arterial oxygen saturation and pulse rate monitoring for patients weighing more than 30 kg. with the Datex Satlite and AS/3 monitors."

10.0 510(k) Summary of Safety and Effectiveness Information - continued

Technological Characteristics Summary:
The E403-09 utilizes a red and infrared LED of the same or tighter specifications as the predicate device. The designated oximeter energizers the LED's which transmit light through a pulsatile arterial bed. The photodiode is of comparable design as the predicate device. The photodiode senses the signal strength of the two LED's which vary with the amount of energy transmitted through the tissue. The oximeter receives the signal from the photodiode and calculates a value for functional oxygen saturation (SpO_2).

Discussion of Non-Clinical Tests:
Testing has been carried out to ensure that the proposed devices meets the requirements of the following standards:
Mechanical, electrical, thermal, and environmental conditions: EN 60601-1
Electromagnetic compatibility: EN 60601-1-2
Biocompatibility: ISO 10993-1 (EN 30993-1).
The device also meets relevant performance and safety requirements from the standard for Pulse Oximeters, EN 865 (ASTM F1415-92).

Discussion of Clinical Tests:
Controlled hypoxia studies were conducted in which device data was compared to blood samples analyzed on a multiwavelength hemoximeter. These tests were conducted to establish the accuracy of the E403-09.

Conclusions Demonstrating Safety Effectiveness and Performance:
The testing carried out for the E403-09 indicates that it meets its design and performance requirements. Clinical validation studies demonstrates the successful use of the sensor and its ability to provide accurate information.

Signed: _____ Date: 1/7/99
Jeffrey Secunda
Epic Medical Equipment Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 9 1999

Mr. Jeffrey Secunda
Vice President R & D
Epic Medical Equipment Services
1800 10th Street, Suite 300
Plano, TX 75074

Re: K990082
E403-09 SpO_2 Finger Sensor
Regulatory Class: II (two)
Product Code: DQA
Dated: January 7, 1999
Received: January 11, 1999

Dear Mr. Secunda:

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, ²Misbranding by reference to premarket notification² (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,

Thomas J. Callahan

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

11.0 Intended Use

Statement of the Indicated Use:

"Reusable sensor for continuous non-invasive functional arterial oxygen saturation and pulse rate monitoring for patients weighing more than 30 kg. with the Datex Satlite and AS/3 monitors."

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990082