K061191

MAY 2 2 2006

measurement SPECIALTIES

innovation performance reliability

Section 10 – Premarket Notification 510(k) Summary

Premarket Notification 510(k) Summary As required by section 807.92

SpO2 Sensors for use with Nellcor® R-Cal SpO2 (Finger sensor, reusable; Ear sensor, reusable; Neonatal-Adult sensor, disposable; Adult/Pediatric sensor, disposable)

GENERAL COMPANY INFORMATON as required by 807.92(a)(1)

COMPANY NAME/ADDRESS/PHONE/FAX:

Measurement Specialties, Inc
1000 Lucas Way
Hampton, VA 23666
Telephone: 757-766-1500
Fax: 757-766-4347

NAME OF CONTACT:

Susan Zaks, Product Line Manager, Optical products

DATE:

April 25, 2006

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME(S):

Finger Sensor for use with Nellcor® R-Cal SpO2
Ear Sensor for use with Nellcor® R-Cal SpO2
Neonatal-Adult Adhesive Sensor for use with Nellcor® R-Cal SpO2
Adult/Pediatric Adhesive Sensor for use with Nellcor® R-Cal SpO2

COMMON NAME:

SpO2 Sensor (accessory to pulse oximeter and ear oximeter)

CLASSIFICATION NAME:

The following Class II classification appear applicable
DQA 21 CFR 870.2700, Finger Sensor for use with Nellcor® R-Cal SpO2
DQA 21 CFR 870.2700, Neonatal-Adult Adhesive Sensor for use with Nellcor® R-Cal SpO2

DQA 21 CFR 870.2700, Adult/Pediatric Adhesive Sensor for use with Nellcor® R-Cal SpO2
DPZ 21 CFR 870.2710, Ear Sensor for use with Nellcor® R-Cal SpO2

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

SpO2 sensors for use with Nellcor® R-Cal SpO2 (Finger sensor, reusable; Ear sensor, reusable; Neonatal-Adult sensor, disposable; Adult/Pediatric sensor, disposable) are substantially equivalent to the predicate SpO2 sensors:

K042704 Flexi-Stat(tm) Finger clip SpO2 sensor
K042675 Flexi-Stat(tm) Ear sensor
K042705 All-fit Flexi-Stat(tm) Disp SpO2 sensor (Nellcor-compatible)
K041522 Flexi-Stat(tm) Disposable Adhesive SpO2 sensor (Nellcor-compatible)

DEVICE DESCRIPTION as required by 807.92(a)(4)

SpO2 sensors are electro-optical sensors that function without skin penetration, electrical contact, or heat transfer. 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 body contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector. The sensor body is connected to a cable that is terminated with a 9-pin D-connector for connecting the sensor to a patient monitor or an interconnect cable.

The Finger and Ear sensors are durable, multiple-patient-use sensors. The sensor structure has a spring structure that easily and comfortably accomodates the sensor to the application site. The Neonatal-Adult and Adult/Pediatric sensors are disposable single-patient-use sensors. The attachment mechanism of these sensors is a soft adhesive tape that is wrapped around the application site.

INTENDED USE as required by 807.92(a)(5)

Finger sensor:

The Finger sensor for use with Nellcor® R-cal SpO2 is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring in patients weighing >= 20 kg.

Ear sensor:

The Ear sensor for use with Nellcor® R-cal SpO2 is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring in patients weighing >= 10 kg.

Neonatal-Adult sensor:

The Neonatal-Adult sensor for use with Nellcor® R-cal SpO2 is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring in adult, pediatric, and neonatal patients.

Adult/Pediatric Sensor:

The Adult/Pediatric sensor for use with Nellcor® R-cal SpO2 is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring in patients weighing >= 20 kg.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Finger sensor, Ear sensor, Neonatal-Adult sensor and Adult/Pediatric sensor use the same theory and principle of operation as the predicate devices. Design characteristics are equivalent in terms of safety and effectiveness, as demonstrated by validation tests.

SUMMARY OF THE PERFORMANCE TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

SpO2 accuracy testing was conducted during induced hypoxia studies on healthy adult volunteer subjects during no motion conditions conducted in an independent research laboratory. The measured arterial hemoglobin saturation value (SpO2) of the sensors was compared to arterial hemoglobin oxygen value determined from blood samples with a laboratory co-oximeter. The accuracy of the sensors in comparison to the co-oximeter samples was measured to be +/-3 digits over the SpO2 range 70-100%.

Bench testing with a simulator and the same patient monitors was performed to verify pulse rate measurement accuracy.

Patient interface temperature (Sensor surface temperature) testing was conducted to ensure the sensor surface temperature during the use of the sensors is not higher than for the predicate devices.

CONCLUSION:

The summary above shows that there are no new questions of safety and effectiveness for the SpO2 sensors Finger Sensor for use with Nellcor® R-Cal SpO2, Ear Sensor for use with Nellcor® R-Cal SpO2, Neonatal-Adult Adhesive Sensor for use with Nellcor® R-Cal SpO2 and Adult/Pediatric Adhesive Sensor for use with Nellcor® R-Cal SpO2 as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 2 2006

Measurement Specialties, Incorporated
C/O Ms. Krista Oakes
Amica Solutions
2300 McDermott Road, #200-207
Plano, Texas 75025

Re: K061191
Trade/Device Name: Finger Sensor for use with Nellcor R-cal SpO2, Ear Sensor for use with Nellcor R-cal SpO2, Neonatal-Adult Sensor for use with Nellcor R-cal SpO2, Adult/Pediatric Sensor for use with Nellcor R-cal SpO2
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DPZ
Dated: April 28, 2006
Received: April 28, 2006

Dear Ms. Oakes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

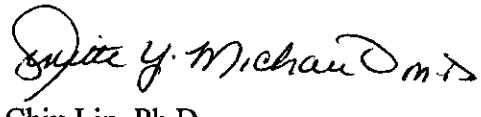
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5 – Indications For Use Statement

Indications for Use

510(k) Number (if known): K061191

Device Name(s): Finger Sensor for use with Nellcor R-cal SpO2, Ear Sensor for use with Nellcor R-cal SpO2, Neonatal-Adult Sensor for use with Nellcor R-cal SpO2, Adult/Pediatric Sensor for use with Nellcor R-cal SpO2.

Indications for Use:

Finger sensor:

The Finger Sensor for use with Nellcor® R-cal SpO2 is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring in patients weighing >= 20 kg.

Ear sensor:

The Ear Sensor for use with Nellcor® R-cal SpO2 is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring in patients weighing >= 10 kg.

Neonatal-Adult sensor:

The Neonatal-Adult Sensor for use with Nellcor® R-cal SpO2 is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring in adult, pediatric, and neonatal patients.

Adult/Pediatric Sensor:

The Adult/Pediatric Sensor for use with Nellcor® R-cal SpO2 is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring in patients weighing >= 20 kg.

Prescription Use ___XX____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

...Sign-Off)
...ion of Anesthesiology, General Hospital,
...ion Control, Dental Devices
...Number: K061191