DEC - 6 2004

K042675

510(k) Summary

Submitter Information:

Elekon Industries, USA, Inc.
3848 Del Amo Blvd.
Torrance CA 90503 USA

Contact:

Tom Dietiker, President
Tel: 310-370-8022
Fax:310-861-5619

Date Prepared:

September 13, 2004

Product Name:

Common Name: SpO2 Ear Sensor (accessory to pulse oximeter – ear oximeter)
Trade Name(s): Flexi-Stat SpO2 Ear Sensor

Predicate Device:

Elekon Flexi-Stat™ ear sensor is substantially equivalent to the Nellcor Dura-Y ear sensor marketed under K944760.

Description:

The Flexi-Stat(tm) SpO_2 Sensor is an electro-optical sensor that functions 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 contains three optical components: two light emitting diodes (LED) that serve as light sources and one photodiode that acts as a light detector. The optical components are housed in a durable ear clip housing. The sensor cable is terminated in a DB-9 style connector.

Intended Use:

The Flexi-Stat SpO2 Sensor is indicated for continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring.

Comparison to Predicate Device:

The Flexi-Stat SpO_2 Ear Sensor uses the same theory and principle of operation as the predicate device. Design characteristics are equivalent in terms of safety and effectiveness, as demonstrated by product testing and accuracy claims.

Performance Data & Conclusions:

Performance testing was conducted during clinical hypoxia studies conducted in an independent research lab. The Flexi-Stat was compared to arterial blood samples analyzed on a laboratory co-oximeter and found to be equivalent to predicate device accuracy claims.

Pulse rate accuracy was validated using bench testing with a pulse rate simulator.

Biocompatibility, electrical safety, and EMC testing was also performed to demonstrate conformance with established industry standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2004

Elekon Industries U.S.A., Incorporated
C/O Ms. Krista Oakes
Principal
Amica Solutions
2300 McDermott Road, #200-207
Plano, Texas 75025

Re: K042675
Trade/Device Name: Flexi-Stat SpO2 Ear Sensor
Regulation Number: 21 CFR 870.2710
Regulation Name: Ear Oximeter
Regulatory Class: II
Product Code: DPZ
Dated: September 14, 2004
Received: October 4, 2004

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.

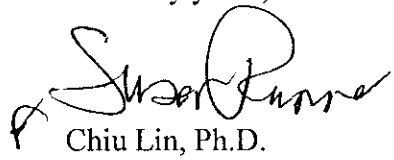
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

Indications for Use

510(k) # (if known):

Device Name: Flexi-Stat SpO2 Ear Sensor

Indications for Use:

Continuous, non-invasive functional arterial oxygen saturation and pulse rate monitoring in patients weighing >10 kg

Prescription Use __x____ (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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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