K051736

DEC 2 2005

510(k) Summary

1. Submitter's Identification:

Lee & Xiao
2600 Mission Street, Suite 100
San Marino, CA 91108
Tel: (626)799-0998
Fax: (626)799-1588

Contact Person: Yingchao Xiao, Esq.

Date: June 8, 2005

2. Device Name:

Trade Name: Fox Oximeter
Common Name: Oximeter
Classification Name: Oximeter

3. Predicate Device Information:

The legally marketed device to which the submitter claims equivalence:

3420 Digit™ Pulse Oximeter (K013171)

4. Device Description:

Fox Oximeter is a portable, lightweight, and battery-operated device that measures %SpO_2, pulse rate, and pulse strength on the finger of a patient.

5. Intended Use:

The Finger Pulse Oximeter is a small portable battery powered device that measures %SpO_2, pulse rate, and pulse strength on the finger. It may be used as a spot check device in the home, hospital, or clinical environments, including patient ground transport in clinical and EMS (Emergency Medical Services) settings. The pulse oximeter will provide reliable measurements on patients ranging from pediatric to adults.

This device is not intended for continous patient monitoring. There are no audible or visible patient alarms.

6. Comparison with Predicate Device:

Both Fox Oximeter and 3420 Digit™ Pulse Oximeter are designed to monitor $\%SpO_2$, pulse rate, and pulse strength of a patient. The subject device differs from the subject device in three essential areas: 1) finger holding mechanism; 2) testing compartment material; and 3) sound on-off mode. Testing was done to ensure that Fox Oximeter would perform safely and effectively within the environment(s) for which it is to be marketed.

7. Discussion on Non-Clinical Tests Performed:

Fox Oximeter complies with the following standards/regulations:

- EN 60601-1-2: 2002
- EN 55011:1998 + A1:1999 + A2:2002
- 47CFR Part 15 Subpart B: 07/2004

- EN 61000-4-2: 1995 + A1:1998 + A2:2001 (IEC 1000-4-2)
- EN 61000-4-3: 2002 (IEC 1000-4-3)
- EN 61000-4-8: 1993 + A1:2001 (IEC 1000-4-8)

8. Discussion on Clinical Tests Performed:

Not Applicable.

9. Conclusion:

Fox Oximeter has the same intended use and similar technological characteristics as 3420 Digit™ Pulse Oximeter. Moreover, the comparisons between the subject device and the predicate device demonstrate that any of the differences in their technological characteristics do not raise any questions in terms of the subject device's safety and effectiveness. Therefore, the Fox Oximeter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 2005

Mr. Yingchao Xiao, Esq.
Shunsuke Nakanishi
Lee & Xiao Attorneys
2600 Mission Street, Suite 100
San Marino, California 91108

Re: K051736
Trade/Device Name: Fox Pulse Oximeter
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: November 22, 2005
Received: November 25, 2005

Dear Mr. Xiao:

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.

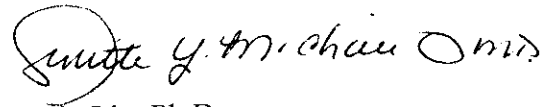
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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

INDICATIONS FOR USE

510(k) Number (if known): K051736

Device Name: Fox Pulse Oximeter

Indications for Use:

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This device is not intended for continous patient monitoring. There are no audible or visible patient alarms.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

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...sion of Anesthesiology, General Hospital,
...fection Control, Dental Devices
...0(k) Number K051736