510(k) Summary

1. **Submitter's Identification:**

Applicant: Lawrence Pellerito, Principal
3101 West Thomas Road, Suite 108
Phoenix, AZ 85017
Tel: 602-272-2141
Fax: 602-272-1275

MAY 11 2007

Correspondent: James A. Dunning, President
QualPro Consulting, LLC
537 N. Spencer
Mesa, AZ 85203
Tel: 480-703-3631
Fax: 480-461-1961

Date: 11 May 2007

2. **Device Name:**

Trade Name: AccuPulse Oximeter
Common Name: Finger Pulse Oximeter
Classification Name: Oximeter

3. **Predicate Device Information:**

The legally marketed device to which the submitter claims equivalence is:

Fox Oximeter (K051736)

4. **Device Description:**

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

5. **Indications for Use:**

The Finger Pulse Oximeter is a small portable device that measures % SpO_2, pulse rate, and pulse indication on the finger. It may be used as a spot-check device in the home or clinical environment. The pulse oximeter will provide reliable measurements on pediatric patients weighing 35 lbs or more, and on adult patients. This device is not intended for continuous patient monitoring. There are no audible or visible patient alarms.

6. **Comparison with Predicate Device:**

Both the AccuPulse Pulse Oximeter and the Fox Oximeter are designed to monitor %SpO_2 and pulse rate. The same critical components and component sources are used for both the Fox Oximeter and the AccuPulse Pulse Oximeter. The AccuPulse Pulse Oximeter uses a circular Light Emitting Diode (LED) indicator to show that the battery is on. The Fox Oximeter does not have a specific battery on indicator, at least one LED will be on at all times, indicating power is on.

Testing was done to ensure that the AccuPulse Pulse Oximeter would perform safely and effectively within the environment(s) for which it is to be marketed.

7. **Discussion on Non-Clinical Test Performed:**

The AccuPulse Oximeter complies with the following:

- EN 50082-1
- EN 61000-4-2
- EN 61000-4-3
- EN 61000-4-8
- EN 55022-1998 with Amendment A1;2000 (CISPR-22)

The following studies were performed on the Elastosil® E 951 (previously known as Elastosil® SWS 951) Control No: 27943 SE material, by BIOSERVICE, Scientific Laboratories GmBH, Munich, BehringStrasse 6, D-82152 Planegg:

- Cytotoxicity
- Hemolysis
- Pryogenicity
- Sensitization
- Dermal Irritation
- Implantation (90 days)

The following studies were performed on the Dow Corning® C6-550 Liquid Silicone Rubber, as described in Dow Corning's "SUMMARY OF QUALIFICATION DATE FOR DOW CORNING ® C6-550 LIQUID SILICONE RUBBER, Revision Date REC 01 Aug 2003":

- Acute Toxicity
- Systemic Toxicity
- Intracutaneous Reactivity
- 30-Day Implant

8. **Discussion on Clinical Test Performed:**

A clinical study was sponsored by ITEC Engineering, LLC, represented by Daniel Englert and Eugene Palatnik. This clinical study was performed at the Milwaukee VA Medical Center, Anesthesia Research Lab. The clinical data was collected in April 2005. This clinical study showed that the correlation between blood gas and oximetry readings, calculated statistically, is 1.87%, which is well within the target accuracy of not more than 2.0%. This clinical study was performed using prototype devices that lead to the final finished device known as the Fox Oximeter device, which is legally marketed by Biotran, Inc.

ACCUPULSE COMPANY worked with ITEC Engineering, LLC, to establish ACCUPULSE COMPANY as a separate owner/operator to manufacture the pulse oximeter device. ITEC Engineering, LLC and Biotran, Inc. granted ACCUPULSE COMPANY permission to use the components, component sources, and clinical study records originally established for the Fox Pulse Oximeter. ITEC Engineering, LLC, currently programs and supplies the microprocessor and the associated signal processing software (FOX V1.03) for the Fox Finger Pulse Oximeter. ITEC Engineering, LLC, has also programmed and supplied the microprocessor and the associated signal processing software (AccuPulse V1.03) to ACCUPULSE COMPANY for the AccuPulse Pulse Oximeter.

9. **Conclusion:**

The AccuPulse Pulse Oximeter (subject device) has the same intended use and theory of operation as the Fox Oximeter (predicate device). Moreover, the critical components and the same component sources are used for both devices. Only minor display differences differentiate the AccuPulse Pulse Oximeter from the predicate device, the Fox Pulse Oximeter. The technological characteristics of the AccuPulse Pulse Oximeter are the same technological characteristics employed by the Fox Pulse Oximeter. The minor display differences do not affect safety or effectiveness of the AccuPulse Oximeter for its intended use. Therefore, the AccuPulse Pulse Oximeter is substantially equivalent to the Fox Oximeter (predicate device).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2007

Eagle Medical Equipment Compamy
C/O Mr. James A. Dunning
President
QualPro Consulting, LLC
537 N. Spencer
Mesa, Arizona 85203

Re: K062724
Trade/Device Name: AccuPulse Pulse Oximeter Model OX1A
Regulation Number: 21 CFR 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: April 30, 2007
Received: May 1, 2007

Dear Mr. Dunning:

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.

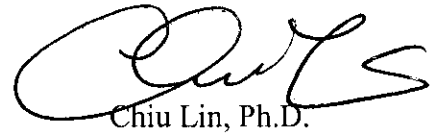
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 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

ACCUPULSE COMPANY

Indications for Use

510(k) Number (if known): K062724

Device Name: AccuPulse Finer Pulse Oximeter

Indications For Use: The Finger Pulse Oximeter is a small portable device that measures % SpO_2, pulse rate, and pulse indication on the finger. It may be used as a spot-check device in the home or clinical environment. The pulse oximeter will provide reliable measurements on pediatric patients weighing 35 lbs or more, and on adult patients. This device is not intended for continuous 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 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

510(k) Number: K062724