K021469

Compliance Systems +, LLC

2703 Josephine Street
Denver, CO 80205
Phone: (303) 359-9791

FEB 12 2003

SUMMARY OF 510(K) SAFETY AND EFFECTIVENESS
Minolta PULSOX-2™

May 01, 2002

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Minolta PULSOX-2 is similar in function, design and construction to other products which were in the market place prior to May 28, 1976. The Minolta PULSOX-2 is also similar to several other products currently being marketed in the United States including the legally marketed predicate device and a substantial equivalence claim is made. The predicate device is the Minolta PULSOX-3. The predicate device is a legally marketed Class II post-amendment device, **K-984570** currently manufactured by Minolta Co., Ltd., Osaka, Japan.

The Minolta PULSOX-2, is the device for determination of saturation of hemoglobin (SpO_2) non-invasively from light signals of two wavelengths transmitted through from tissues of patients who have pulmonary disease or pulmonary dysfunction. SpO_2 is, as defined in 1.3.14 of ISO 9919:1992, percent of hemoglobin saturation with oxygen measured by a pulse oximeter and displayed as a percentage. The measurement principle depends on a changing signal caused by the pulsatile nature of blood flow.

Performance indicates that the Minolta PULSOX-2, is equivalent to the Minolta PULSOX-3. The testing results are also in compliance with those in published literature for pulse oximeters. The testing conducted demonstrates that the Minolta PULSOX-2 is safe and effective.

Nanci Dexter
Owner, Compliance Systems +, LLC

05/01/02
Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 12 2003

Minolta Company Limited
C/O Ms. Nanci Dexter
Compliance Systems, LLC
2703 Josephine Street
Denver, Colorado 80205

Re: K021469
Trade/Device Name: PULSOX-2
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: December 20, 2002
Received: January 2, 2003

Dear Ms. Dexter:

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 (301) 594-4646. 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,

Susan Runner

Susan Runner, DDS, MA
Interim 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 Statement

510(k) Number: K021469

Device Name: PULSOX-2

Indications for Use:

The Minolta PULSOX-2 is indicated for the non-invasive monitoring of oxygen saturation of arterial hemoglobin (SpO2) and pulse rate. The Minolta PULSOX-2 is intended for use with adult patients. The Minolta PULSOX-2 is for spot-checking only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K021469