K982331

KELLER MEDICAL SPECIALTIES

42609 Crawford Road • Antioch, Illinois 60002

Toll Free **800/843-6226** • **847/395-3547**

• FAX **847/395-6918**

SEP 11 1998

SUMMARY OF SAFETY AND EFFECTIVENESS

Company: Keller Medical Specialties
42609 Crawford Road
Antioch Road, Illinois 60002

Registration: 1421498

Device: Model 850+ Pulse Oximeter

Substantially Equivalent: Keller Model 850 (k895987) and numerous competitor's models

Contact: Jean Keller
President

DESCRIPTION: The Keller Model 850+ Pulse Oximeter is a portable, battery operated, patient pulse oximeter. It measures oxygen saturation and the pulse rate of the patient by means of an infrared sensor attached to the finger or ear.

INTENDED USE: The Keller Medical Specialties Pulse Oximeter Model 850+ measures and monitors arterial oxygen saturation (SaO2) and pulse rate using standard dual wavelength pulse oximetry techniques.

This unit is portable with battery operation. The oximeter allows complete control of patient alarm limit settings.

The unit is not intended for use on neonates.

TECHNOLOGICAL CHARACTERISTICS: This device incorporates dual wavelength technology and uses variable averaging methods to allow the user to incorporate the method best suited to the situation.

PERFORMANCE DATA: Bench data showed that the Model 850+ is equivalent to the Model 850 and a Biochem device. Alarms were tested and verified as accurate.

CLINICAL DATA: The Model 850+ was tested on 30 patients and compared to readings obtained by predicated Model 850. The date results indicated no significant deviation between the two devices.

CONCLUSIONS: Comparison of all hardware and software changes, risk analysis, and the data obtained from performance and clinical testing proves that the Keller Model 850+ is substantially equivalent to predicate device in addition to being safe and effective on it's own merits.

Signed: Jean Keller Date: 6-29-98

Jean Keller
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 11 1998

Ms. Jean Keller
Keller Medical Specialties
42609 Crawford Road
Antioch, IL 60002

Re: K982331
Model 850+ Pulse Oximeter
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: June 29, 1998
Received: July 2, 1998

Dear Ms. Keller:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K982331

Device Name: Keller Medical Specialties Model 850+ Pulse Oximeter

Intended Use:

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982331

Prescription Use ✓
Per 21 CFR 801.109

OR

Over-The Counter___