AUG 10 1999

K990648

KELLER MEDICAL SPECIALTIES

42609 Crawford Road • Antioch, Illinois 60002

Toll Free **800/843-6226** • **847/395-3547** • FAX **847/395-6918**

510(k) Summary of Safety and Effectiveness

Submitter:			Date of Preparation: February 15, 1999
Company / Institution name: **Keller Medical Specialties**			FDA establishment regulation number: 14 21498
Division name (if applicable): N.A.			Phone number (include area code): (847) 395-3547
Street address: 42609 Crawford Road			FAX number (include area code): (847) 395-6918
City: Antioch	State/Province: Illinois	Country: USA	ZIP/Postal Code: 60002
Contact name: Ms Jean Wagner			
Contact title: President			

Product Information:	
Trade name: Combined Pulse Oximeter/BP Monitor	Model number: KMS 890+
Common name: Vital Signs Monitor	Classification Name: Physiological Monitor

Information on devices to which substantial equivalence is claimed:		
510(k) Number	Trade or proprietary or model name	Manufacturer
1 K910262	1 Vital Signs Monitor Model KMS-890	1 Keller Medical Specialties
2 K982331	2 Pulse Oximeter Model KMS-850+	2 Keller Medical Specialties
3 K910852	3 Model 507O	3 Criticare
4	4	4

1.0 Description

The Model KMS-890+ is a portable, battery operated, non-invasive monitor used to measure a patient's blood pressure and/or oxygen saturation level with the pulse rate

2.0 Intended Use

The Keller Medical Specialties Model KMS-890+ Combined Pulse Oximeter and Non-invasive Blood Pressure Monitor is intended to monitor the arterial oxygen saturation (SaO2), pulse rate and measure the blood pressure parameters. All

2.0 Intended Use (cont.)
values are obtained by non-invasive methods. The blood pressure parameters measured are systolic, diastolic and mean arterial pressure.

This device can be operated by the internal rechargeable battery. Alarm settings for the displayed parameters can be adjusted as required.

Contraindications:
This device is not intended for use on neonates.

3.0 Technological Characteristics
No new technological characteristics are introduced with this unit. The device is designed from incorporating the functions of the two existing Keller Medical Specialties devices into one single device.

4.0 Substantial Equivalence
The Model KMS 890+ is substantially equivalent to the two Keller Medical Specialties predecessor models currently on the market, as well as numerous vital signs monitors sold by competitors; including the Criticare Model 507O.

5.0 Performance Data
The Model KMS 890+ was bench tested using commercially available simulators to assure the reliability of the readings. The reliability is substantially equivalent to the reliability of the Keller Medical Specialties predecessor models.

6.0 Clinical Tests
No clinical tests performed.

7.0 Conclusions Drawn
The devices are designed and tested to guarantee the safety and effectiveness when used according to the instruction manuals.

By: Jean Keller Wagner Date: 2-26-99
Jean Keller
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 10 1999

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

Re: K990648
Model KMS 890+
Regulatory Class: II (two)
Product Code: 74 DXN and DQA
Dated: June 25, 1999
Received: June 28, 1999

Dear Ms. Wagner:

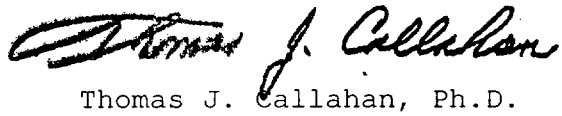
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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): K990648

Device Name: Model-KMS890+ Combination Monitor

Intended Use:
The Keller Medical Specialties Model-KMS890+ Combined Pulse Oximeter and Non-invasive Blood Pressure Monitor is intended to monitor the arterial oxygen saturation (SaO2), pulse rate and measure the blood pressure parameters. All values are obtained by non-invasive methods. The blood pressure parameters measured are systolic, diastolic and mean arterial pressure.

This device can be operated by the internal rechargeable battery. Alarm settings for the displayed parameters can be adjusted as required.

Contraindications:
This device is not intended for use on neonates.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Joanne M. Weatherman

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K990648

8/9/99

✓ Prescription Use
Per 21 CFR 801.109

OR

Over-The Counter