

AUG 20 1998

K980619

**Section 2
Summary**

The following is a Summary of the Sabratek Patient Home Monitoring System (PHMS) substantial equivalence and safety and efficacy.

CLASSIFICATION NAME: The Agency has not specifically classified the device. The device performs the functions of Monitor, Cardiac (incl. Cardiotachometer & rate alarm), 870.23.00, Monitor, Breathing Frequency, 868.2375, Monitor, Electrocardiographic, 870.2340, Monitor Pulse-Rate, 870.2300, and Monitor, Temperature Clinical Electronic Thermometer, 880.2910.41

COMMON/USUAL NAME: Ambulatory Patient Monitor

PROPRIETARY NAME: Sabratek Patient Home Monitoring System (PHMS)

CLASSIFICATION: 21 CFR Monitor, Cardiac (incl. Cardiotachometer & rate alarm), 870.23.00, Monitor, Breathing Frequency, 868.2375, Monitor, Electrocardiographic, 870.2340, Monitor Pulse-Rate, 870.2300, and Monitor, Temperature Clinical Electronic Thermometer, 880.2910.41

PERFORMANCE STANDARDS: No Performance Standards are in effect for this device.

INDICATIONS The Sabratek Patient Home Monitoring System (PHMS), is a physiological data monitoring and communications system intended for use predominately in alternate care settings. It consists of an ambulatory monitor (the APM-2000), a communications module located in the patient care setting (the Virtual Hospital Room Communicator), and personal-computer-based data display and storage software (Remote Device Access Software, RDAS) located in the healthcare provider facility. The APM-2000 is a physiological data recorder which stores ECG waveform data, temperature, respiration rate, arterial blood oxygen saturation, and pulse from non-invasive sensors. It alerts the patient of sensor and system errors. It has an alarm system which alarms whenever measured data violates prescribed limits. The VHR Communicator is a PC-based module which communicates with the APM-2000 to download, store and transfer physiological

data. The VHR Communicator can also collect data of indirect blood pressure, oral temperature, and patient weight using external modules. It communicates with the RDAS through dial-up telephone lines and transfers data to the healthcare facility. The RDAS displays the physiological data to the caregiver and archives it.

CONTRAINDICATIONS

NON-CLINICAL TESTING

Engineering bench testing
Verification and Validation testing

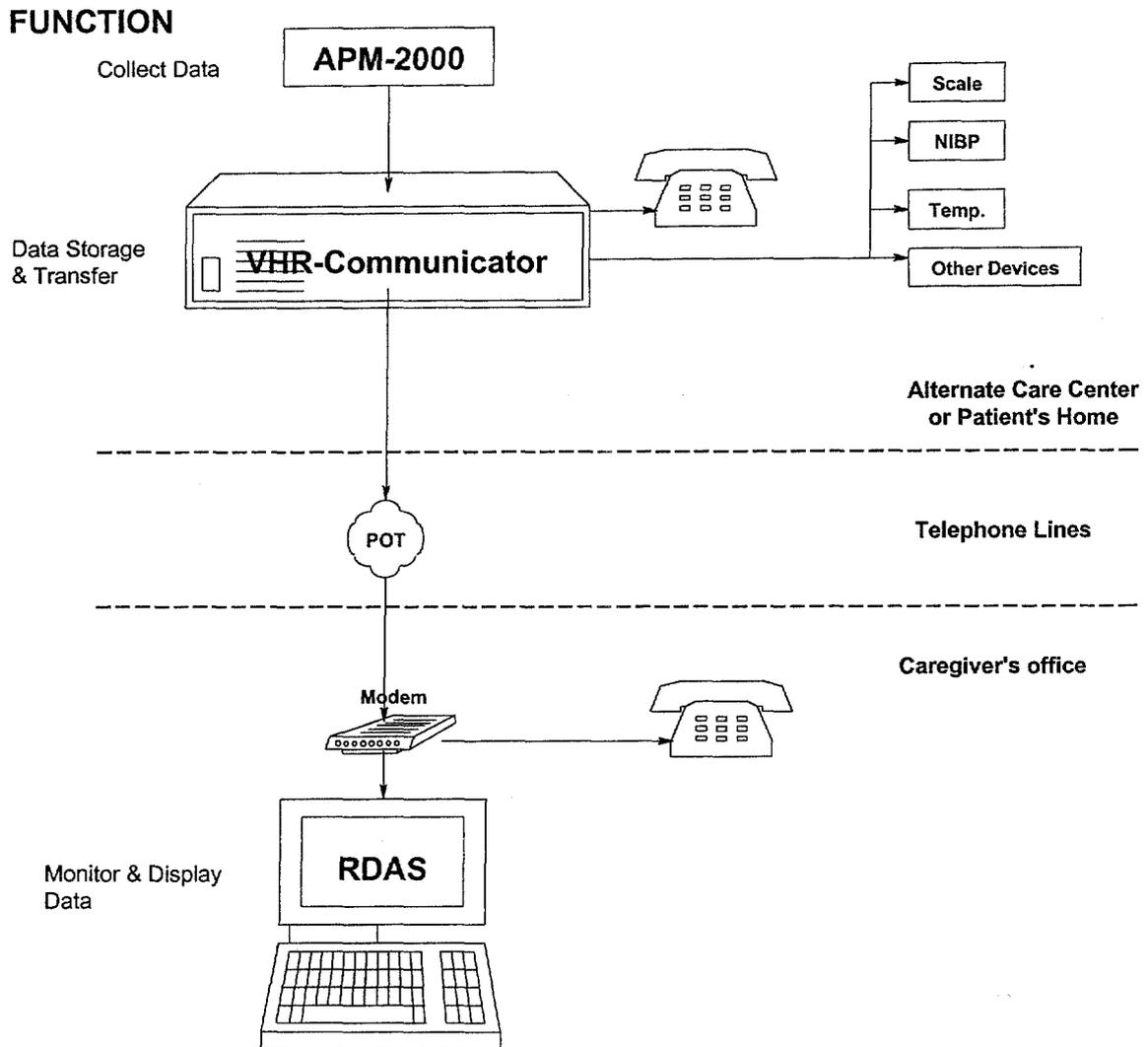
CONCLUSIONS

The Sabratek Patient Home Monitoring System (PHMS) is equivalent in safety and efficacy to its predicate devices.

System description

The system consists of three major components as shown in Fig.1

Fig. 1 Patient Home Management System



- The Ambulatory Patient Monitor (APM-2000) is an ambulatory device that monitors physiological data of the ambulatory patients.
- The Virtual Hospital Room Communicator (VHRC) is a data storage and transfer device that resides in a patient's home or at an alternate care center. The VHRC has the capability to detect and monitor the APM-2000. A number of peripheral devices such as a Scale, Non Invasive Blood Pressure device (NIBP), Oral Temperature probe and other devices can also be connected to the VHRC. Sabratek has selected peripheral devices with current agency rulings of substantial equivalence for use with the VHRC. The VHRC is accessible by a standard telephone line (POT).
- The Remote Device Access Software (RDAS) is a Microsoft Windows 95/NT applications program. The program interacts with the Virtual Hospital Room Communicator (VHRC) via modem and standard telephone line. The program collects the data stored in the VHRC and presents the information for review by the

caregivers. The program can also control the functions of the APM-2000 and monitor the functions of other devices connected to the VHRC.

**COMPARISON BETWEEN SABRATEK PATIENT HOME MONITORING SYSTEM (PHMS)
 AND
 PREDICATE DEVICES**

Parameter	Sabratek Patient Home Monitoring System (PHMS)	Predicate Device
Respiration		Propaq® Encore (K#951246)
Measure respiration rate	Yes	Yes
Range	4-40 RPM	2-150 RPM
Accuracy	± 2 RPM or 2%	± 2 RPM or 2%
Sensor	Pro-Tech 1246 (K#960851)	Pro-Tech 1246 (K#960851)
Electrocardiogram		Propaq® Encore (K#951246)
Records and stores monitor bandwidth electrocardiogram	Yes	Yes
Single lead (2 active electrodes plus a "ground" electrode)	Yes	Yes
5 lead selectable leads	No	Yes
Defibrillator-protected input leads	No	Yes
Defib Sync.	No	Yes
Pacemaker spike detection	No	Yes
QRS or arrhythmias detection	No	Yes
QRS Tone	No	Yes
Detects an electrode lead off condition	Yes	Yes
Alarms on low/high rate	No	Yes
Wireless operation	No	Optional
ECG Electrodes	Lead-Lok, Inc LLE306BX, P-6 (K#911529)	Lead-Lok, Inc LLE306BX, P-6 (K#911529)
Patient Weight Scale	AND Medical UC-300	AND Medical UC-300
K#	Class I Exempt device 880.2700	Class I Exempt device 880.2700
Temperature Probe	Thermometric MA-200	Thermometric MA-200
K#	Exempt device	Exempt device
Pulse Oximetry	Nonin OEM II	Nonin OEM II
Non Invasive Blood Pressure	AND Medical	AND Medical
K#	K871720	K871720

VHRC - General		Propaq® Encore
Communications capability	Up to 10 external devices	Up to 10 external devices
Display	4 row 20 character LCD	LCD 45.75 X 67.56 mm
Display backlight	Yes	Yes
Keypad	5 row by 5 column custom	Separate keys
Voice synthesizer	Yes	No
Malfunction audio	Yes	No
Speaker phone	Optional	No
Patient alarm notification	Audio and visual	Audio and visual
Size	≈12" x 12" x 4"	9.6" X 8.2" X 7.6"
Weight	≈10 lb	12.68 Lbs
Operating temperature	0 to 60 C	0 to 40 C
Humidity	0 to 95% non-condensing	15% to 95% non-condensing
Operating altitude	-200 to 15,000 ft	-2000 to 15000 Ft.
Shipping/storage temperature	-20 to +60 C	-20 to +60 C
Drip proof	IEC 529 level IPX1	Unknown
VHRC power		
115/230 VAC 50/60 Hz operation	Yes	100 – 120 VAC, 50-60 Hz
Operation from internal battery pack	Yes, > 1 hour	Yes 2.5 + Hrs.
Internal battery charger	Yes	Yes
Battery recharge time	≈8 hours	8 – 12 Hrs.
Double insulation	Yes	Yes
Power input	<40 watts	Unknown

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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 20 1998

Mr. E.F. Waddell
Director, Regulatory Affairs
Sabratek Corporation
8111 North St. Louis Avenue
Skokie, IL 60076

Re: K980619
Sabratek Patient Home Monitoring System
Regulatory Class: II (two)
Product Code: MHX
Dated: July 10, 1998
Received: July 13, 1998

Dear Mr. Waddell:

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" (21CFR 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

K980619

Device Name: Sabratek Patient Home Monitoring System (PHMS)

Indications for use: The Patient Home Monitoring System (PHMS) is a physiological data monitoring and communications system intended for use predominately in alternate care settings. It consists of an ambulatory, patient-worn monitor (the APM-2000), a communications module located in the patient care setting (the Virtual Hospital Room Communicator), and personal-computer-based data display and storage software (Remote Device Access Software, RDAS) located at the healthcare provider facility. The APM-2000 is a patient-worn physiological data recorder which stores ECG waveform data, temperature, respiration rate, arterial blood oxygen saturation, and pulse from non-invasive sensors.

Federal law (US) restricts this device to sale by or on the order of a physician.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K980619
Stuart Portnag for DB7
8-20-98