Summary

This summary of the 510(k) safety and effectiveness information for the AvidCare Corporation Home Health Monitor (HHM), is being submitted in accordance with the requirements of 21 CFR part 807.92.

1. Company making the submission:

Name:	AvidCare Corporation 152 West Wisconsin Ave. Milwaukee, WI 53203	Or	Submission Correspondent: Delphi Consulting Group 11874 South Evelyn Circle Houston, Texas 77071
Telephone:	1-414-291-0844		1-713-723-4080
Contact:	William K. Genthe, Ph.D.		J. Harvey Knauss
Date:	December 2000		Consultant

2. Device:

Proprietary Name:	Home Health Monitoring System
Common Name:	Blood pressure monitors
Classification Name:	Noninvasive blood pressure measurement system

3. Predicate Device:

Modification of Home Health Monitor for indications (addition of Lung Function and different Blood Glucose device) K964697 - 21 CFR Section 807.81 (a)(3). The company name has been change from Advance Medical Devices to AvidCare, Corporation.

4. Classification Names & Citations:

21 CFR 870.2100 Cardiovascular Blood Flowmeter

5. Description:

The HHM System is an integrated patient care system incorporating a Home Based physiologic monitor that telecommunicates objective patient health data as determined by licensed health care professional. The system is comprised of the following devices and systems. Note: Each system-input device has a separate FDA release to market. Exact devices for use is determined by a licensed health care professional.

- Non-invasive blood pressure device K925402
- Lung function monitor K960078
- Blood Glucose device K974451
- Pulse Oximetry device K913695

- Stand-on weight scale N/A

6. Indications for Use:

The Home Health Monitor System is intended for patient home use for the following:

1. Non-invasive blood pressure measurement,
2. Non-invasive blood oxygen saturation measurement using pulse oximetry,
3. In vitro diagnostic quantitative measurement of glucose in fresh capillary whole blood,
4. Non-invasive measurement of lung peak flow, and
5. Patient weight using a stand-on electronic scale.

The results of these measurements are transmitted to a computer monitoring station in a clinical setting via common telephone lines from the patient's home setting.

7. Contra-indications:

As stated in each device's FDA release to market.

8. Comparison:

The HHM has the same device characteristics as the predicate device (HHM K964697), except this submission changes indications to include lung function monitoring.

9. Test Data:

The HHM device has been subjected to extensive safety, performance, a validation testing. Final device testing for the system includes various performance tests designed to ensure that the device meets all f its functional requirements and performance specifications.

The HHM device labeling includes instructions for safe and effective use. The labeling includes Warning, Cautions and guidance for use.

10. Literature Review:

A review of literature pertaining to the safety of physiologic monitors has been conducted. Appropriate safeguards have been incorporated in the design and modification of the HHM.

11. Conclusions:

The conclusion drawn from these tests is that the HHM device is equivalent in safety and efficacy to its predicated device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2001

William Genthe, Ph.D.
AvidCare Corporation
152 West Wisconsin Avenue
Milwaukee, WI 53203

Re: K010029
Trade Name: Home Health Monitoring System
Regulation Number: 21 CFR 870.1130
Regulatory Class: Class II (two)
Product Code: DXN
Dated: May 3, 2001
Received: May 4, 2001

Dear Dr. Genthe:

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) 594-4646. 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,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K 010029

Device Name: Home Health Monitor System

Indications for use:

The Home Health Monitor System is intended for patient home use for the following:

1. non-invasive blood pressure measurement,
2. non-invasive blood oxygen saturation measurement using pulse oximetry,
3. in vitro diagnostic quantitative measurement of glucose in fresh capillary whole blood,
4. non-invasive measurement of lung peak flow, and
5. patient weight using a stand-on electronic scale.

The results of these measurements are transmitted to a computer monitoring station in a clinical setting via common telephone lines from the patient's home setting.

Prescription Device.

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)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010029

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional Format 1-2-96)