K992478

510(k) Summary

OCT 15 1999

HP Model 3810A
Hewlett Packard Company
Prepared June 15, 1999

Product Name: Current Trade Name: Model 3810A

Manufacturer: Hewlett Packard Company
3500 Deer Creek Road
Palo Alto, California 94043

Generic Name: Telemedicine System

Classification Name: DXN

Submitted by: Hewlett-Packard Company,Healthcare Solutions Group, Customer Services Division , New Clinical Ventures

Contact Person: Sheila W. Pickering Ph.D.
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A. Legally Marketed Predicate Device
The HP device is substantially equivalent to the following predicate devices.

Table 1 Predicate Devices

Ref. #	Sponsor	Predicate Device	510(k) Number
1	Acme Medical	Digital Scale	K790130
2	Instromedix	Lifesigns System	K964408
3	American Telecare	Personal Telemedicine System	K952882

B. Device Description

The Hewlett-Packard (HP) Model 3810A telemedicine device provides a system for daily collection of weight, blood pressure and ECG used in the management of home care patients.

The main flow of information originates in the home where a patient uses a blood pressure unit, a scale and an ECG rhythm recorder on a daily schedule. Each of the units automatically reports their data wirelessly to a home Hub, which in turn relays the data using a standard modem over the telephone to a secure database. Health care professionals (such as physicians, nurses, and case managers) having approval for access use a secure log-on procedure to gain access to their patient's data. The provider follows up on any unexpected or undesired changes in the patient's data trends with a phone call.

The home Hub incorporates a receiver, an embedded processor with memory, a standard modem and an automatic dial up module. It is designed so that its operation does not interfere with normal use of the phone including an answering machine. Its connections are identical to those of an answering machine, consisting of a standard wall power plug and a daisy chain phone connection. The installation and use of the home Hub poses no significant risk to the patient or other people within the patient's home.

The data forwarded through the home Hub arrives though a standard modem contained in the HP system server. This server is separate from the Telemedicine PC in the clinic and is programmed to decode the data from the home units. The system design provides for data security.

C. Indications for use and Intended Use

Intended Use: The Model 3810A is intended to be used upon prescription of a licensed physician or authorized healthcare provider by patients as a means to automatically collect and transmit medical information, such as weight, blood pressure and non-diagnostic ECG, over normal residential telephone lines, between a patient, typically at home, and a health care professional at the authorized provider. Indications for Use: The Model 3810A is indicated for patients at home, who are capable and willing self-administrate this device, upon prescription of their healthcare provider, to collect and transmit medical information such as weight, blood pressure (including pulse rate) and non-diagnostic ECG rhythm strip to the healthcare provider at another location. The patient takes these measurements, typically once per day, and the information is transmitted automatically via normal telephone lines to the healthcare provider. The device does not send any real-time alarms. Clinical judgement and experience are required to check and interpret the information delivered. Contraindications: The device is not intended as a substitute for medical care. The device is contraindicated for patients with uncompensated heart failure, patients at high risk of life threatening arrhythmias, patients with recent myocardial infarctions, or patients requiring direct medical supervision or emergency intervention.

D. Substantial Equivalence

The following tables show the basis for substantial equivalence

Substantial Equivalence Comparison Table

	Predicate Devices		Submission Device
Product Name	Instromedix LifeSigns	American Telecare PTS	Model 3810A
Intended Use	Telemedicine system	Telemedicine system	Telemedicine system
Transmission	Residential telephone lines	Residential telephone lines	Residential telephone lines
Intended Users	Home users and health care provider	Home users and health care provider	Home users and health care provider
Site of Use	Home; clinic	Home, clinic	Home, clinic
Measurements	Blood pressure, ECG	Blood pressure	Weight, blood pressure, ECG
Software	Patient database	Patient database	Patient database

E. Performance Data

The M3810A patient units- the M3813A Scale Unit, the M3815A Blood Pressure Unit, and the M3816A Rhythm Strip Recorder Unit- have been tested for electrical safety and has received a certificate of compliance with IEC 60601-1:1988 +A1:1991 +A2:1995 and FCC Part 15

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 15 1999

Sheila W. Pickering, Ph.D.
Regulatory Affairs Consultant
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2081 Longden Circle
Los Altos, CA 94024

Re: K992478
Physiological Signal Transmitter and Receiver
Regulatory Class: II (two)
Product Codes: DXN, DPS, FRW
Dated: July 23, 1999
Received: July 26, 1999

Dear Dr. Pickering:

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

Indications for Use

510(k) Number (if known) K992478

Device Name: Hewlett Packard Model M3810A

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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)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR 801)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K992478