10.0 510(k) Summary of Safety and Effectiveness

This Special 510(k) submission notifies the FDA of our intention to modify the HP M2600A Viridia Telemetry System.

1.0 Manufacturer/Submitter

Denise Haley
Quality and Regulatory Engineer

Hewlett Packard Company
Patient Monitoring Division
Healthcare Solutions Group
3000 Minuteman Road
Andover, MA 01810-1099

Telephone: 978-659-2701
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2.0 Establishment Registration Number

1218950

3.0 Manufacturing Site Address

Hewlett Packard Company
Patient Monitoring Division
Healthcare Solutions Group
3000 Minuteman Road
Andover, MA 01810-1099

4.0 Sterilization Site

Does not apply.

5.0 Date

October 15, 1999

6.0 Device Name, Trade Name

Proprietary Name: HP M2600A Viridia Telemetry System
(Formerly known as the HP M2600A OmniCare Telemetry System)

Common Name: HP Viridia Telemetry System

Classification Name: Radio frequency physiological signal transmitter and Receiver (per CFR 870.2910)

Component Classifications:

Device classification information is presented in the following table. This table also identifies the tier categorization based on the list distributed by the DDE on January 27, 1994:

Table 1: Panel 74, Cardiovascular

Classification	Procode	Description	Tier
870.2910 II	DRG	Radio frequency physiological signal transmitter and receiver	2
870.2700 II	DQA	Oximeter	2
870.1025 III	DSI	Arrhythmia Detector with alarm	2

7.0 Substantial Equivalence

The modified device is substantially equivalent to the previously cleared HP M2600A Viridia Telemetry System, marketed pursuant to Premarket Notification K980429. Additional predicate devices are listed below:

Manufacturer	Device	Model	510(k)
Hewlett Packard	Telemetry Monitoring System	M1403A	K894277
Hewlett Packard	Telemetry Monitoring System, Rev. 1.2	M1403A	K911139
Hewlett Packard	Telemetry Monitoring System, added Analog Output	M1403A	K913533
Hewlett Packard	Telemetry Monitoring System, added ST monitoring	M1403A	K920429
Hewlett Packard	M2600A Viridia Telemetry System	M2600A	K980429
Hewlett Packard	M2605A Viridia Wave Viewer	M2605A	K974567

8.0 Modification Description

The modification in this submission is the addition of a battery extender to enable the operation of the transmitter from an external power source.

9.0 Intended Use

The modified device, HP M2600A Viridia Telemetry System, Release B, has the same intended use as the legally marketed predicate devices.

The intended use of the modified device has not changed from that of the predicate device:

The device is intended to provide ambulatory and bedside monitoring of ECG and SpO_2 parameters of adult and pediatric patients in a professional healthcare facility. It is intended to be used by trained health care personnel. It is not intended for home use.

10.0 Fundamental Technology

The modified device subject to this submission has the same fundamental technology as the legally marketed predicate devices.

11.0 Design Controls

Verification, validation, and testing activities were successfully conducted to establish the safety, performance, and reliability characteristics of the battery extender. Testing involved system level tests, integration tests, safety testing from hazard analysis, interference testing, and hardware testing. Pass/fail criteria were based on the specifications cleared for the predicate device and test results demonstrated substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 8 1999

Denise Haley
Quality and Regulatory Engineer
Hewlett Packard Company
Medical Products Group
3000 Minuteman Road, MS 0491
Andover, MA 01810-1099

Re: K993516
HP M2600A Viridia Telemetry System
Regulatory Class: III (three)
Product Code: DSI
Dated: October 15, 1999
Received: October 18, 1999

Dear Ms. Haley:

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,

for Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.1 ODE Indications for Use Statement

Indications for Use Statement

510(k) Number: K993516
(if known)

Device Name: HP M2600A Viridia Telemetry System

Indications for Use:

The indications for use of the Viridia Telemetry System are:

- **Condition:** The licensed clinician decides that the Viridia Telemetry System should be used to monitor the patient.
- **Prescription vs. Over-the-Counter:** The HP Viridia Telemetry System is a prescription device.
- **Part of body or type of tissue interacted with:** The ECG signal is obtained from accessory electrodes in contact with the patient's skin. The SpO_2 signal is obtained from an accessory sensor in contact with the patient's skin.
- **Frequency of use:** As prescribed by a licensed physician.
- **Physiological purpose:** To monitor the ECG or SpO_2 of patients on the order of a licensed clinician.
- **Patient Population:** Adult and pediatric patients.

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 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993516