CHAPTER 14: [510(K)] Summary of Safety and Effectiveness

SEP 9 1998

This submission notifies the FDA of our intention to modify the HP M2600A Viridia Telemetry System.

1.0 Manufacturer/Submitter

1.1 Name and Address

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

1.2 Establishment Registration Number

1218950

1.3 Hewlett-Packard Manufacturing Site Address

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

1.4 Sterilization Site

Does not apply.

1.5 Contact Persons

You may contact Ray Stelting at (978) 659-3445, or Mike Hudon at (978) 659-3173, or Chas Burr at (978) 659-2529.

1.6 Date

February 2, 1998

2.0 Regulatory Information

2.1 References

510(k) Notifications:

- DC # K961165 – HP M2600A OmniCare Telemetry System
- DC # K894277 – HP M1403A

2.2 Device Name, Trade Name

Proprietary: HP M2600A Viridia Telemetry System
Common Name: HP Viridia Telemetry System.

Classification name: Radio frequency physiological signal transmitter and receiver (per CFR 870.2910)

2.3 Predicate Device(s)

Predicate device information is tabulated below.

Table 3: Predicate Device Information

MFG	Device	Models	K#
Hewlett-Packard	Telemetry Monitoring System	M1403A System	K894277
Hewlett-Packard	Telemetry Monitoring System, Revision 1.2	M1403A System	K911139
Hewlett-Packard	Telemetry Monitoring System, added Analog Output	M1403A System	K913533
Hewlett-Packard	Telemetry Monitoring System, added ST monitoring	M1403A System	K920429

2.4 Products (Components) Included as Part of This Device:

No accessories or additional components are affected by this modification of the HP M2600A Viridia Telemetry System device.

2.5 Device Classification

74DRG

2.6 Performance Standard:

None established under section 514.

3.0 Description

The Hewlett-Packard HP M2600A Viridia Telemetry System consists of a pocket sized

digital synthesized transmitter, synthesized receiver, and a mainframe that accommodates up to eight receiver channels. Patient physiological parameter information is displayed on HP M2350A/60A, a central station device.

The modification allows the user to utilize an EtO Sterilization process for the purpose of cross-infection prevention and changes the labeling to reflect a change in battery life specification and in the device name.

4.0 Intended Use

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

5.0 Indications for Use

An indications for use statement is included in this notification but was not part of the earlier notification, K961165.

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 versus over-the-counter:** 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 licensed clinician.
- **Physiological purpose**: To monitor the ECG or SpO_2 of patients on the order of a licensed clinician.
- **Patient population**: Adult and pediatric patients.

6.0 Substantial Equivalence

6.1 Comparison of technological characteristics

HP M2600A Viridia Telemetry System is now substantially equivalent to the M1403A regarding cross-infection prevention in that both transmitters now utilize similar EtO sterilization processes. The comparison shows the device to be substantially equivalent in safety, effectiveness, and intended use to a legally marketed device.

6.2 Verification and Validation

The device was thoroughly tested to verify that performance claims in the labeling are met. A qualified independent laboratory performed tests related to the EtO sterilization process. Verification testing was done to show that performance of the M2601A was not changed due to exposure to the EtO sterilization process. The purpose was to verify that the device continued to perform to its specification and is that safety was not degraded. The test results support that purpose.

6.3 SE Conclusion

Based on comparison to the predicated device and on the test results, the Viridia Telemetry System is substantially equivalent to the HP M1403A.

7.0 Conclusion:

The logic of the SE Decision Tree leads to a determination of SE. We agree with that logic. The modified device is very similar to the predicate device. The modified device was thoroughly validated. We conclude, therefore, that it is safe and effective when used as intended and indicated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 9 1998

Ms. Elisabeth George
Hewlett-Packard Company
3000 Minuteman Road
Andover, MA 01810

Re: K980429
HP M2600A Viridia Telemetry System Mofication
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: May 28, 1998
Received: June 8, 1998

Dear Ms. George:

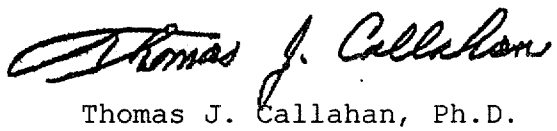
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,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

510(k) Number (if known): K980429

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 versus over-the-counter:** 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.
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- **Patient population:** Adult and pediatric patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

mark kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.1109) (Optional Format 1-2-96)