

CHAPTER 24: SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 20 1998

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

1.3.1 Manufacturing Site Establishment Registration Number

9680888

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

12/4/97

2.0 Regulatory Information

2.1 References

- K945277, Hewlett-Packard Model M1490A Wireless Patient Data Communicator "PalmVue" System.
- K961165, Hewlett-Packard Model M2600A OmniCare Telemetry Monitoring System.
- K922974 and K945134, Hewlett-Packard Model M1275A Component Transport System.

- K923343 HP M1020A SpO₂ Parameter Plug-in Module.

2.2 Device Name, Trade Name

Proprietary: Hewlett-Packard M2605A Viridia Wave Viewer

Trade: Viridia Wave Viewer

2.3 Products (Components) Included As Part Of This Device:

No accessories or additional components are included as part of the Hewlett-Packard M2605A Viridia Wave Viewer.

2.4 Device Classification

We believe the proper classification for the computing platform is 870.2450, Class 2, Tier 2, Procode 74DXJ even though the display technology is liquid crystal. We find no classification for the Viridia Wave Viewer software.

2.5 Performance Standard:

None established under Section 514.

3.0 Description

Viridia Wave Viewer is a software application that executes on a palmtop computer. Viridia Wave Viewer software enables the palmtop computer to communicate with the M2601A transmitter using an infrared link for the purpose of displaying ECG waveform, or an SpO₂ pleth waveform, and numerics for SpO₂ and Pulse. Viridia Wave Viewer also allows the user to estimate the heart rate, HR, by using electronic calipers to measure the distance between two R-peaks. Viridia Wave Viewer does not operate on the information received except to format it for display on the palmtop screen. It performs no calculations except for estimating HR. It has no detection capability. It can not, therefore, annunciate any alarms.

4.0 Intended use

Viridia Wave Viewer may be used to provide limited ECG and SpO₂ information to the clinician. Patient assessment includes uses similar to:

- Determination of a patient's tolerance to exercise during ambulation (e.g. while walking down a hallway).
- Patient assessment while waiting for monitoring equipment to arrive (e.g. a patient collapses in the hallway).
- Additional input to a routine physical assessment of a patient (e.g. for use on rounds).

Patient assessment does not include uses such as:

- Continuous monitoring of a patient (not intended for use as a bedside monitor).
- Determining detailed ECG diagnosis such as ST segment values, R-R variability or any other diagnostic ECG values.

The patient population is adult and pediatric patients.

There are no alarms. The device turns off after 10 minutes to prevent long term "monitoring" use. Viridia Wave Viewer is *not* intended to be a patient monitor.

In the USA, Federal law restricts Viridia Wave Viewer to sale by or on the order of a physician.

It is intended to be used in a professional health care facility. It is not intended for home use.

5.0 Indications for Use

5.1 Condition

Viridia Wave Viewer is generally indicated when the clinician decides to assess the ECG or SpO₂ vital signs of adult and pediatric patients while at the patient location and does not need a diagnostic quality display.

5.2 Part of Body or Type of Tissue with Which the Device Interacts

Viridia Wave Viewer does not contact the body or tissue of the patient.

5.3 Frequency of Use

Viridia Wave Viewer is indicated for use when prescribed by a clinician.

5.4 Physiological Purpose

Viridia Wave Viewer is indicated when the physiological purpose is to gain information for treatment, to assess adequacy of treatment, or to rule out causes of symptoms. Viridia Wave Viewer is not suitable for patient monitoring.

5.5 Patient Population

Adult, and pediatric ambulatory and non-ambulatory patients.

5.6 Prescription Versus Over-the-Counter

Viridia Wave Viewer is a prescription device.

6.0 Verification and Validation

Viridia Wave Viewer has been verified and validated to provide the test results needed to show substantial equivalence to legally marketed devices.

7.0 Safe and Effective When Used as Labeled

Documented test results obtained from extensive testing coupled with detailed user documentation of Viridia Wave Viewer and the computing platform produces a very high confidence level that the device is safe and effective when used as intended.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

JAN 20 1998

Mr. Ray Stelting
Regulatory Engineer
Medical Products Group
Hewlett-Packard Company
3000 Minuteman Road
Andover, MA 01810

Re: K974567
Trade Name: Viridia Wave Viewer
Regulatory Class: III
Product Code: 74 MSX
Dated: December 4, 1997
Received: December 5, 1997

Dear Mr. Stelting:

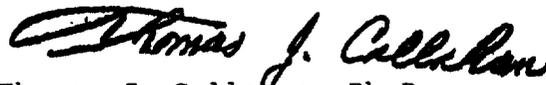
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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/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

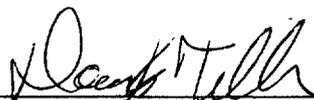
510(k) Number (if known): K974567

Device Name: Hewlett-Packard M2605A Viridia Wave Viewer

Indications For Use: The device is intended to be used as an assessment tool that enables licensed clinicians in a clinical environment to determine the quality of ECG and SpO2 signals at the location of telemetry monitored patients. In addition, limited assessment of patients ECG and SpO2 vital signs can be determined. Viridia Wave Viewer is not intended for monitoring and has no alarm functions. The device is not intended for home use and is not suitable for patient monitoring.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974567

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____