CHAPTER 23: SUMMARY OF SAFETY AND EFFECTIVENESS

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 David Osborn at (978) 659-3178 or Elisabeth George at (978) 659-4663 for additional information. Or, a fax may be sent to (978) 685-5624. Alternate contact: Chas Burr at (978) 659-2529.

1.6 Date

4/14/98

2.0 Regulatory Information

2.1 References

- K950821 and K960934, Hewlett-Packard M1205A Viridia 24 (formally OmniCare 24)
- K922974 and K945134, Hewlett-Packard Model M1275A Component Transport System.
- K961247, Datex AS/3 Compact Monitor

2.2 Device Name, Trade Name

Proprietary: Hewlett-Packard M1205A Viridia 24 CT

Trade: Viridia 24 CT

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

Accessories or additional components are included as part of the Hewlett-Packard M1205A Viridia 24 CT as indicated in the technical data sheet.

2.4 Device Classification

We believe the proper classification for the device is 870.1025, Monitor, Physiological, Patient.

2.5 Performance Standard:

None established under section 514.

3.0 Description

Viridia 24 CT is a patient monitor. This submission notifies the FDA that the power source was modified. No other significant changes were made to the device.

4.0 Intended use

4.1 Purpose

"Viridia 24 CT measures and displays multiple physiological parameters and waves, and generates alarms, and recordings. It exchanges information with compatible devices. Viridia 24 CT is not a therapeutic device." on page 3-1.

4.2 Patient Population

"Viridia 24 CT is intended to be used on adult, pediatric, and neonatal patients." on page 3-1.

4.3 Environment

"Viridia 24 CT is intended to be used in a clinical environment by licensed clinicians. It is not intended for home use." on page 3-1.

"It communicates with devices such as a central station through network interface ports and a serial I/O port. It is suitable for intra facility transport." on page 3-1.

"Viridia 24 CT is a prescription device and will carry the following label, 'United States Federal law restricts this device to sale by or on the order of a physician.'" on page 3-1.

"Viridia 24 CT is not a therapeutic device." on page 3-1.

5.0 Indications for Use

5.1 510(k) Number

The 510(k) number has not been assigned.

5.2 Device Name

The device name is Hewlett-Packard M1205A Viridia 24 CT.

5.3 Indications for Use Statement

The paragraphs below are the elements of the indications for use statement for Viridia 24 CT.

5.3.1 Condition

"Condition: Viridia 24 CT is generally indicated when the clinician decides there is a need to measure and display multiple physiological parameters and waves, to generate alarms and recordings of adult, pediatric, or neonatal patients." on page 4-1.

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

"Part of Body or Type of Tissue with Which the Device Interacts: Viridia 24 CT does not contact the body or tissue of the patient. Signals are obtained from accessory electrode, transducer, and sensor devices." on page 4-1. Viridia 24 CT does not contact the body or tissue of the patient.

5.3.3 Frequency of Use

"Frequency of Use: Viridia 24 CT is indicated for use when prescribed by a clinician." on page 4-1.

5.3.4 Physiological Purpose

"Physiological Purpose: Viridia 24 CT is indicated when the purpose is to gain information for treatment, to assess adequacy of treatment, or to rule out causes of symptoms. Viridia 24 CT is well suited for patient monitoring." on page 4-1.

5.3.5 Patient Population

"Patient Population: Adult, pediatric, and neonatal non-ambulatory patients." on page 4-1.

5.3.6 Prescription Versus Over-the-Counter

"Prescription Versus Over-the-Counter: Viridia 24 CT is a prescription device." on page 4-1.

6.0 Verification and Validation

Viridia 24 CT 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 24 CT and host devices produces a very high confidence level that the device is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 1999

Mr. David Osborn
Medical Products Group
Hewlett-Packard Company
3000 Minuteman Road
Andover, MA 01810

Re: K981376
Hewlett-Packard M1205A Viridia 24CT
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: September 11, 1998
Received: September 14, 1998

Dear Mr. Osborn:

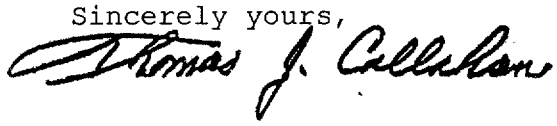
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,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

CHAPTER 4: INDICATIONS FOR USE

510(k) Number (if known) K981376

Device Name: Hewlett-Packard M1205A Viridia 24 CT

Indications for Use Statement:

Condition: Viridia 24 CT is generally indicated when the clinician decides there is a need to measure and display multiple physiological parameters and waves, to generate alarms and recordings of adult, pediatric, or neonatal patients.

Part of Body or Type of Tissue with Which the Device Interacts: Viridia 24 CT does not contact the body or tissue of the patient. Signals are obtained from accessory electrode, transducer, and sensor devices.

Frequency of Use: Viridia 24 CT is indicated for use when prescribed by a clinician.

Physiological Purpose: Viridia 24 CT is indicated when the purpose is to gain information for treatment, to assess adequacy of treatment, or to rule out causes of symptoms. Viridia 24 CT is well suited for patient monitoring.

Patient Population: Adult, pediatric, and neonatal non-ambulatory patients.

Prescription Versus Over-the-Counter: Viridia 24 CT is a prescription device.

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

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 801.109) (Optional Format 1-2-96)