JUL 22 1999

K990476

7.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

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Regulatory Affairs
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This summary was prepared on February 3, 1999

2. The name of this device is Hewlett-Packard Viridia Component Monitoring System, Rev.K, with EASI-ECG Option. The common name is HP Virdia CMS, Rev.K. Classification names are as follows:

Regulation Number	Classification Name
870.2300	Monitor, Cardiac (including Cardiotachometer & Rate Alarm)
870.2350	Adapter, Lead Switching, Electrocardiograph
870.1025	Detector and Alarm, Arrythmia

3. The new device with the EASI-ECG Option is substantially equivalent to the following predicate devices: the Totemite EASI Lead System Cable K872781B (12/29/87), and the Zymed T8010 Telemetry Central Station Monitor K951370 (10/6/95). The accessories and materials are optional and are the same accessories originally cleared for use with HP M1175A/76A CMS K882609 (1/19/89). The EASI-ECG will operate with the HP M1001A/B and M1002A/B ECG plug-in modules previously cleared under K973437 (12/3/97).

4. The new device consists of a software enhancement enabling the CMS system to accommodate an electrode placement pattern allowing signals for deriving the 12-lead electrocardiogram from the 5-lead EASI electrode system. The EASI option is fully compatible with the existing HP ECG frontend modules M1001A/B or M1002A/B.

5. The CMS Rev.K with the EASI-ECG option has the same intended use as the legally marketed predicate devices. When used in the hospital environment, the HP EASI-ECG option is intended for use where 12-Lead ECG monitoring is indicated in adult patients.

6. The CMS Rev.K with the EASI-ECG option operates using a monitoring technology rather than a telemetry system as used in the predicates. The measurement technology and the transmission of ECG signals, however, are similar and therefore the technological characteristics are essentially the same as those of the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 22 1999

Mr. Egon Pfeil
Regulatory Affairs
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Re: K990476
HP Viridia CMS and 24/26 Rev K with EASI-ECG
Regulatory Class: III (three)
Product Code: MHX
Dated: May 21, 1999
Received: May 26, 1999

Dear Mr. Pfeil:

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, ²Misbranding by reference to premarket notification² (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

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 Statement

510(k) Number (if known) K990476

Device Name

The Hewlett-Packard Viridia Component Monitoring System (M1175A/76A/77A), and Viridia 24/26 (M1205A) Rev. K with EASI-ECG Option

Indications for Use

The Hewlett-Packard Viridia Component Monitoring System, (M1175A/76A/77A), and Viridia 24/26 (M1205A) Rev.K with EASI-ECG Option is indicated for:

- Assessment of symptoms that may be related to rhythm disturbances of the heart: patients with palpitations, the evaluation of arrhythmia's in adult and pediatric patients.
- Assessment of risk in patients with or without symptoms of arrhythmia.
- Assessment of efficacy of antiarrhythmic therapy.
- Assessment of pacemaker function.
- Assessment of symptomatic or asymptomatic patients to evaluate for ischemic heart disease.
- Assessment is indicated for single-hospital environment.

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 K990476

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)