NOV - 8 1999

K992674

9.0 510(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:

Egon Pfeil
Regulatory Affairs
Medical Products Group-Europe
Hewlett-Packard GmbH
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This summary was prepared on July 28, 1999

2. The name of this device is the Hewlett-Packard Viridia M1175A/76A/77A Component Monitoring System with M1027A EEG module. The common name is patient monitor. Classification name is as follows:

Regulation Number	Classification Name
882.1400	Electroencephalograph

3. The new device is substantially equivalent to previously cleared HP devices marketed pursuant to K990125, and K922974, and to the Telefactor Neurotrac-II K914571, and to the SpaceLab EEG module 90481, K932842.

4. The modification is the addition of new applications software and firmware that involves the addition of the M1027A EEG Module to the HP M1175A/76A/77A Component Monitoring System to allow the measurement of electroencephalographic signals.

5. The new device has the same intended use as the legally marketed predicate devices. When connected by appropriate electrodes, and used in the operating room and intermediate/critical care environments, the device is intended for measuring EEG signals in adult, pediatric, and neonatal patients.

6. The new device has the same technological characteristics as the legally marketed predicate devices.

7. Validation, and testing activities were conducted to establish the performance and reliability characteristics of the new module using system level tests, integration tests, environmental tests, safety testing from hazard analysis, interference testing, and hardware testing. Pass/Fail criteria were based on standards,

where applicable, and on the specifications cleared for the predicate devices. The test results showed substantial equivalence.

Clinical performance evaluations were conducted with the EEG module to validate two channel functionality under conditions existing in the indicated hospital environments. More than 90% of the users found the applicability, usability, and efficiency of EEG M1027A module monitoring acceptable or better. Apart from one instance of minor skin irritation, no adverse events were reported during the studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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Mr. Egon Pfeil
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Herrenberger Strasse 110-140
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Germany

NOV 8 1999

Re: K992674
Trade Name: Hewlett-Packard Viridia Component Monitoring System
Regulatory Class: III
Product Code: GWQ, MHX
Dated: August 5, 1999
Received: August 10, 1999

Dear Mr. Pfeil:

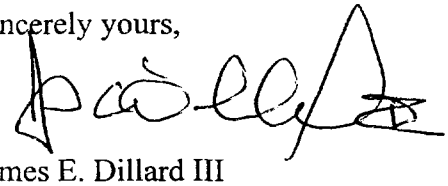
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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) 594-4595. 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,



James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3.1 ODE Indications Statement

Indications for Use Statement

510(k) Number (if known) K992674

Device Name

The Hewlett-Packard Company (HP) Viridia CMS Patient Monitoring System, Rel.K, with M1027A EEG Measurement Module.

Indications for Use

The Hewlett-Packard Viridia CMS Patient Monitoring System, Rel.K, with M1027A EEG Measurement Module is intended for measurement and display of the electroencephalogram of adults, pediatrics, and neonates in the Operating Room and intermediate/critical care environments.

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 General Restorative Devices
510(k) Number K992674

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