JUN 7 1999

K991773

10.0 510(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
Herrenberger Strasse 110-140
D-71034
Germany
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This summary was prepared on April 27, 1999

2. The name of this device is the Hewlett-Packard family of Viridia Patient Monitors individually known as the M3000A/M3046A (Viridia M3/4). The common name is patient monitor. Classification names are as follows:

Regulation Number	Classification Name
870.1435	Computer, Diagnostic, Pre-Programmed, Single-Function
870.1025	Detector and Alarm, Arrhythmia
870.2900	Cable, Transducer and Electrode, Patient (including connector)

3. The modified device is substantially equivalent to previously cleared HP devices that contain the same STAR software and that are marketed pursuant to K964122, K971910, and K981576.

4. The modification consists of the addition of software that involves only the arrhythmia and ST measurement algorithm of the measurement computer processing unit of each device.

5. The new device has the same intended use as the legally marketed predicate devices. When used in the hospital environment or mobile environment for patient transport monitoring, the device is intended for measuring and displaying, recording and alarming multiple physiological parameters and waves in adult, pediatric, and neonatal patients.

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

7. Verification, validation, and testing activities were conducted to establish the performance and reliability characteristics of the STAR algorithm using bench studies. Testing involved system level tests, integration tests, safety testing from hazard analysis, interference testing, and hardware testing. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 7 1999

Mr. Egon Pfeil
Hewlett-Packard GmbH
Medical Products Group - Europe
Herrenberger Strasse 110-140
D-71034 Boeblingen
GERMANY

Re: K991773
Viridia HP M3000A/M3046A (M3/M4), Rel.B
Portable Patient Monitor
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: May 10, 1999
Received: May 25, 1999

Dear Mr. Pfeil:

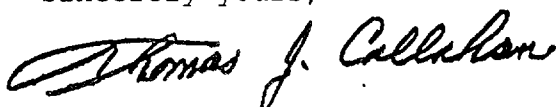
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,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

3.1 ODE Indications Statement

Indications for Use Statement

510(k) Number (if known) K991773

Device Name The Hewlett-Packard Company (HP) Viridia M3000A/M3046A Patient Monitor Rev.B with ST/AR Software. Viridia HP M3000A/M3046A Patient Monitor Rel.B

Indications for Use The Hewlett-Packard family of patient monitor products is intended for monitoring, recording, and alarming of multiple physiological parameters. The devices are indicated for use in health care facilities by health care professionals whenever there is a need for monitoring the physiological parameters of adult, neonatal, and pediatric patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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