K990125

JAN 29 1999

8.0 510(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
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Hewlett-Packard GmbH
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This summary was prepared on December 30, 1998

2. The name of this device is Hewlett-Packard Viridia Component Monitoring System. The common name is Patient Monitor. Classification names are as follows:

egulation umber	Classification Name
68.2375	Monitor, Breathing (Ventilatory) Frequency
68.1720	Analyzer, Gas, Oxygen, Gaseous Phase
70.2340	Electrocardiograph
70.2700	Oximeter
70.2300	Monitor, Cardiac (including Cardiotachometer & Rate Alarm)
70.2350	Adapter, Lead Switching, Electrocardiograph
70.2810	Recorder Paper Chart 510(k) exempt
70.1100	Alarm, Blood Pressure
70.1110	Computer, Blood Pressure
70.1435	Computer, Diagnostic, Pre-Programmed, Single-Function
70.2450	Display, Cathode-Ray Tube, Medical
70.1025	Detector and Alarm, Arrythmia
70.2900	Cable, Transducer and Electrode, Patient (including connector)
70.1120	Cuff, Blood-Pressure
70.1130	System, Measurement, Blood Pressure, Non-invasive
80.2910	Clinical Electronic Thermometer

3. The new combination device is substantially equivalent to previously cleared HP devices marketed pursuant to K941811, K973437 and K981376

4. The modification is a software based change that combines software in the HP Clinical Monitoring System product line (M1175A, M1176A and M1177A, M100B/M1002B ECG/RESP) with the software in the HP Component Transport System Viridia, (M1205A), the devices are to be known collectively as the HP Viridia Component Monitoring System. The combination system will allow for shared future functionality capabilities in HP patient monitoring systems.

5. The new combination device has the same intended use as the legally marketed predicate devices. When used in the hospital environment, the HP Viridia Component Monitoring System is intended for monitoring, recording, and alarming of multiple physiological parameters in adult, pediatric and neonatal patients.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1999

Mr. Egon Pfeil
Regulatory Affairs
Medical Products Group
Hewlett-Packard GmbH
Herrenberger Strasse 110-140
Boeblingen, Germany 71034

Re: K990125
HP Viridia Component Monitoring System, Model Rev K
Regulatory Class: III (three)
Product Code: DSI
Dated: December 30, 1998
Received: January 13, 1998

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" (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

3.1 ODE Indications Statement

Indications for Use Statement

510(k) Number
(if known)

Device Name The Hewlett-Packard Viridia Component Monitoring System

Indications for Use The Hewlett-Packard Viridia Component Monitoring *System* is intended for use in 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)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K990125

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