

AUG 3 | 1999

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:

Mike Hudon,  
Regulatory Engineer

Hewlett-Packard Company  
Patient Monitoring Division  
Healthcare Solutions Group  
3000 Minuteman Road  
Andover, MA 01810-1085

Tel: 978 659 3173  
Fax: 978 685 5624  
Email:mike\_hudon@hp.com

This summary was prepared on August 03, 1999

2. The name of this device is the Hewlett-Packard M2331A CareVue 9000 Clinical Information Management System. Classification names are as follows:

<u>Regulation No.</u>	<u>Classification Name</u>
870.2450	Medical cathode-ray tube display
None	Computers and software, medical

3. The new device is substantially equivalent to previously cleared HP devices marketed pursuant to K922210, K922058, K990125, K984194, and K822695.

4. The modification is primarily a software based change that expands access to more information data bases. Also, improvements were made to upgrade the hardware and operating system environments.

5. The new device has the same intended use as the legally marketed predicate devices. When used in the hospital environment for patient records management, the device is intended for collecting, storing, and managing patient records, and for computation of drug dosages.

6. The new 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 new device with respect to the predicate. Testing involved system level tests, integration tests, and safety testing from risk analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 31 1999

Mr. Mike Hudon  
Regulatory Engineer  
Hewlett-Packard Company  
Medical Products Group  
3000 Minuteman Road  
Andover, MA 01810

Re: K992636  
HP Carevue 9000  
Regulatory Class: II (Two)  
Product Code: DXJ  
Dated: August 6, 1999  
Received: August 26, 1999

Dear Mr. Hudon:

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.

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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, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K992636

Device Name:

Hewlett Packard Clinical Information System,  
CareVue 9000, Model M2331A

Indications for Use:

The HP M2331A CareVue 9000 is a clinical information system intended for use in data collection, storage, and management with independent bedside devices, and ancillary systems that are connected either directly or through networks. It is indicated for use by health care providers whenever there is a need for generation of a patient record and computation of drug dosage.

(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)**

(Optional Format 1-2-96)

(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K992636