K974746

510(k) Summary
for
M1765A ECG Manager

MAR 18 1998

1. DATE SUMMARY PREPARED

December 16, 1997

2. SUBMITTER'S NAME AND ADDRESS

Hewlett-Packard Company
3000 Minuteman Road
Andover, MA 01810-1099

3. CONTACT PERSON

Mr. George Diller

Telephone: (978) 659-4971
Facsimile: (978) 659-3168

4. DEVICE NAME

Proprietary Name: M1765A ECG Manager
Common Name: ECG Management System
Classification Name: unknown

5. PREDICATE DEVICES

The legally marketed device to which equivalence is being claimed is the Muse 5000 System manufactured by Marquette Electronics, Inc. (K840932). The design of ECG Manager is substantially equivalent in safety and performance to a subset of the Muse 5000 features, with the important exception that ECG Manager does not perform any computerized interpretation of the ECG waveform.

6. DEVICE DESCRIPTION

The M1765A ECG Manager is a data management system which allows users to receive, store, view, manually edit, copy, print, and delete 12 lead ECG information which originated on HP PageWriter cardiographs. The M1765A ECG Manager employs the Microsoft Windows 95 or NT operating system, and Microsoft's Access relational database. Ease of use is assured by use of time-tested, industry standard graphical user interfaces. The system consists of a software application which is installed by the user on a user-provided IBM-compatible personal computer running the Microsoft Windows 95 or NT operating system. The product is designed to be installed and operated by users with minimal computer skills. Voluminous, context-sensitive online HELP facilities are provided as part of the product. There are no diagnostic algorithms built into M1765A ECG Manager applications. All clinical rules and decision logic is embedded in the software of the electrocardiographs.

7. INTENDED USE

The M1765A ECG Manager is a computer software program which allows viewing, manual editing, printing and archiving of digitized electrocardiograph records from Hewlett-Packard Company electrocardiograph machines.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The ECG Manager and the Muse 5000 both are PC based systems utilizing commercial operating systems.

Both offer viewing and editing on a video screen, hard copy printouts, and connection to the electrocardiograph via direct connect, removable diskette, or modem. An important difference is that ECG Manager does not perform any computerized interpretation of the ECG waveform.

9. NONCLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The design of the ECG Manager has been thoroughly validated at the unit and system level. Non-clinical tests were conducted to demonstrate that the ECG Manager software meets all product requirements.

10. CONCLUSIONS FROM NONCLINICAL TESTING

The testing of the ECG Manager demonstrates that the performance is substantially equivalent to predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 18 1998

Mr. George Diller
Project Manager, R&D
Hewlett-Packard Company
Cardiology Products Division
3000 Minuteman Road
Andover, MA 01810

Re: K974746
M1765A ECG Manager
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: December 16, 1997
Received: December 19, 1997

Dear Mr. Diller:

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 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/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): K974746

Device Name: M1765A ECG Manager

Indications For Use:

The M1765A ECG Manager is a computer software program which allows viewing, manual editing, printing and archiving of digitized electrocardiograph records from Hewlett-Packard Company electrocardiograph machines.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K974746

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

(Optional Format 1-2-96)