

P -- [510(k)] Summary of Safety and Effectiveness

DEC - 3 1997

The M1001B ECG and M1002B ECG/Respiration Modules are intended for monitoring, recording, and alarming of ECG and respiration for adult, pediatric, and neonatal patients. Existing hardware and software of the M1001B ECG and M1002B ECG/Respiration plug-in modules (which were originally cleared together with CMS under K882609) were modified. The CMS hardware and CMS software modules are unchanged. The modified M1001B ECG and M1002B ECG/Respiration plug-in modules were fully validated (including regression testing).

The comparison of intended use and technological characteristics of this device to other legally marketed devices taken together with the validation results and other information in this submission indicate that this device is substantially equivalent to legally marketed predicate devices in safety, effectiveness and intended use.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 3 1997

Mr. Egon Pfeil
Medical Products Group-Europe
Hewlett-Packard GmbH
Schickardstrasse 4
D-71034 Boeblingen
Germany

Re: K973437
Models M1001B ECG and M1002B ECG/Respiration Plug-in Modules of
Component Monitoring System (CMS) M1175A/76A
Regulatory Class: II (two)
Product Code: 74 DPS
Dated: September 8, 1997
Received: September 10, 1997

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.

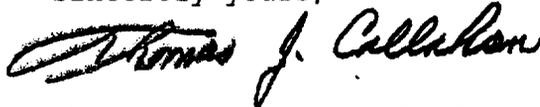
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice 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" (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

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: M1001B ECG and M1002B ECG/Respiration Plug-in Modules

Indications For Use:

The HP M1001B/M1002B ECG Plug-in Modules together with the Patient Monitor M1175A/M1176A are indicated for use in health care facilities by health care professionals when the patient's clinician deems it appropriate to use a device that:

- a) Can measure and display multiple physiological parameters and waves¹ of one patient, and can generate alarms and printouts based on those measurements.
- b) Can be used on adult, pediatric, and neonatal patients as specified in the Technical Data Sheets.

I. List of supported measurements

- (a) ECG
- (b) Respiration

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Wolfgang S. ... M.D.

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

510(k) Number K973437

Prescription Use: **yes**
(Per 21 CFR 801.109)

OR

Over-The-Counter Use: **no**

(Optional Format 1-2-96)