SEP 4 1998

K982025

510(k) Summary for 12-Lead Option (#C90), for CodeMaster (M2475B)

DATE SUMMARY PREPARED

May 29, 1998

SUBMITTER'S NAME AND ADDRESS

Hewlett-Packard Company

Medical Products Group

3000 Minuteman Road

Andover, MA 01810-1099

CONTACT PERSON

Richard J. Petersen ,

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DEVICE NAME

Proprietary Name: 12-Lead option (#C90) to the M2475B

Common Name: 12 Lead option to the CodeMaster 100

Classification Name: Class II, Electrocardiograph / Defibrillator / Monitor

PREDICATE DEVICE(S)

The legally marketed devices to which equivalencies are being claimed is the LifePak 11/11R, defibrillator / pacemaker / diagnostic cardiac monitor, manufactured by Physio-Control, (K951593) and (K912189). Also, the M1770A Electrocardiograph, manufactured by Hewlett-Packard, (K935772, K954980, K981265). The design of the #C90 option is substantially equivalent in safety and performance to the LifePak 11/11R and M1770A features.

DEVICE DESCRIPTION

The #C90 12 Lead ECG option to the M2475B provides 12-Lead acquisition and high fidelity printing for on-site manual interpretation. The preview display allows the user to scroll through all 12 leads and computerized ECG analysis for fast ECG interpretation. The integrated modem (U.S. version only) provides combined cellular / land line for ECG transmission to a physician to over-read and diagnose ECGs. It offers an industry standard RS232 port for hardwire connection with an external (not provided) modem. In addition, it features the ACI-TIPI, Acute Cardiac Ischemia – Time Insensitive Predictive Instrument that aids in patient diagnosis. The complete system is compatible with the Hewlett-Packard cardiology network, which includes the TraceMaster ECG Management System, M1730B and the EGC Manager, M1765A.

INTENDED USE

The 12-Lead Option (#C90) for the CodeMaster 100, Hewlett-Packard M2475B is intended for use by emergency medical personnel who are under physician-approved protocols to acquire electrocardiograms (ECGs) from patients. The resulting 12-Lead report, with or without computerized interpretation, is intended to be used by medical personnel as a tool to help diagnose a variety of cardiac disorders.

The application of 12-Lead electrocardiography in pre-hospital emergency medicine is proving to be a key factor for reducing the time needed to identify and treat patients suffering from Acute Myocardial Infarction (AMI). Once identified, this patient is more likely to be transported to a hospital with the appropriate facilities and the ED staff at that hospital is more likely to be prepared when the patient arrives. The addition of the 12-Lead option to the CodeMaster 100 will aid emergency medical personnel to move quickly and accurately identify and triage patients suffering from AMI.

COMPARISON OF TECHNOLOGY CHARACTERISTICS

The M2475B CodeMaster 100 Defibrillator/Monitor option #C90 employs the same technologies as the predicate devices used for comparison; the Hewlett-Packard PageWriter 200i Cardiograph, Model HP M1770A (510(k) no. K954980) with option #A05 ECG Storage and Transmission, and the Physio Control LifePak 11 diagnostic cardiac monitor (510(k) no. K912189), and the LifePak 11R defibrillator-pacer (510(k) no. K951593).

These devices acquire an ECG signal through a 10-wire cable and patient electrodes placed in standard 12-Lead positions. Common analog-to-digital signal acquisition techniques are used to produce a digitized ECG signal that can be displayed, analyzed heart rate, and processed for computerized interpretation. The resulting information is presented on displays, and formatted into a diagnostic report that can be printed or transmitted to remote sites using landlines and standard modem protocols. Re-use of PageWriter 200i Cardiograph hardware, hardware design, application software, and algorithm software to make the #C90 option for CodeMaster 100 demonstrate the technology is not just similar, but identical.

NONCLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The "Device Comparison Tables" in Section I of this document contains comparison information of the 12-Lead option #C90 for the M2475B to legally marketed devices of similar functionality. The tabular comparison establishes the substantial equivalence of the 12-Lead option to those devices currently marketed with regard to the overall performance of the device to safety and effectiveness criteria. The use of non-clinical tests as defined in the "Verification and Validation" section contained in Appendix D demonstrates that the 12-Lead option #C90 is substantially equivalent to other legally marketed devices that meet the same or similar test performance criteria. The selection of tests in Appendix D were chosen in order to establish clear conformance to mandatory and voluntary standards, software baselines, and hardware functionality. The results summarized in Appendix D show that non-clinical tests were successfully used to determine the substantial equivalence of the 12-Lead (#C90) option to the M2475B.

CONCLUSION FROM NONCLINICAL TESTING

The results of the "Device Comparison Tables" and the Appendix D test data confirm that the verification strategy using non-clinical testing to establish substantial equivalence was a successful process for testing the 12-Lead option #C90 to the M2475B.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 4 1998

Mr. Richard J. Petersen
Hewlett-Packard Company
Medical Products Group
Cardiology Products Division
3000 Minuteman Road
Andover, MA 01810

Re: K982025
12-Lead Option (#C90) for the M2475B Monitor/Defibrillator
Regulatory Class: III (three)
Product Code: 74 MKJ
Dated: June 8, 1998
Received: June 9, 1998

Dear Mr. Petersen:

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. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and 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, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 section 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

On August 16, 1993, the Final Rule for Device Tracking was published in the Federal Register, pages 43442-43455 (copy enclosed). Be advised that under Section 519(e) of the Act as amended by the Safe Medical Devices Act of 1990, FDA has identified the above device as a device which requires tracking. Because the device is subject to tracking, you are required to adopt a method of tracking that follows the devices through the distribution chain and then identifies and follows the patients who receive them. The specific requirements of the regulation are found in 21 CFR 821 as described in the August 16, 1993 Federal Register beginning on page 43447.

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 not 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,

Anh A. Ciarkowski

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

Enclosures

Indications for Use

510(k) 982025:

Device Name: Hewlett-Packard 12-Lead Option (#C90) for the M2475B CodeMaster 100

Indications For Use: The 12-Lead option (#C90) adds 12-Lead ECG functionality to the CodeMaster 100 monitor/defibrillator, M2475B. This feature will be used by emergency medical personnel who have been trained and authorized for its use.

The primary patient population for which this feature is intended is defined as persons with symptoms associated with acute myocardial infarction or cardiac arrhythmias. The 12-Lead feature can also be applied to patients for routine.medical examinations or anytime a baseline ECG is ordered by a physician. Note that a physician must review the preliminary report. Like any computer assisted ECG interpretation program, the predictive instrument evaluation is not a substitute for the physician's decision process.

This product is not intended for home use.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Prescription Use _____ or Over-The-Counter Use _____

(Per 21 CFR 801.109)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K982025