K974420

510(k) Summary for M1730B TraceMaster ECG System

FEB 19 1998

1. Date this summary was prepared: November 20, 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
Telefax (978)659-3168

4. Device Name

Proprietary Name: M1730B TraceMaster ECG System
M1766B Local Edit Station
M1798B Remote Edit Station

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 TraceMaster is substantially equivalent in safety and performance to a subset of the Muse 5000 features, with the important exception that TraceMaster does not perform any computerized interpretation of the ECG waveform.

6. Device Description

The HP M1730B TraceMaster is an advanced data management system that automates the processing and storage of ECGs from HP PageWriter cardiographs. Its high-performance Pentium™ computer stores up to 750,000 ECGs on high-speed, online disks and produces clean, permanent traces on a HP LaserJet printer. The multitasking operating system smoothly handles the rigorous demands of simultaneous editing, printing, reception, and storage of ECGs. A powerful client/server network can spread the workload of editing, transmitting, and printing to M1776B Local Edit Stations, LAN-connected HP LaserJet printers, and M1798B Remote Edit Stations.

Electrocardiograms can be transferred from HP electrocardiographs to the TraceMaster via the Local Area Network or floppy diskettes. On the Edit Stations users can then view the ECG and the interpretation performed by the electrocardiograph, compare to previous waveforms and interpretations, and overread and edit the interpretation. Remote Edit Stations can be connected via the Local Area Network or modem.

7. Intended Use

The M1730B TraceMaster ECG System is a computer system which allows viewing, manual editing, printing and archiving of digitized electrocardiograph records from Hewlett-Packard Company electrocardiograph machines.

8. Comparison of Technological Characteristics

The M1730B TraceMaster ECG System and the Muse 5000 both are PC bases systems utilizing commercial operating systems and networking software. They have similar geometry and construction.

The TraceMaster can handle a throughput of up to 56,000 ECGs per year, while the Muse 5000 can handle at least 30,000. The TraceMaster can store 750,000 ECGs on-line, while the Muse 5000 can store up to 1.1 million. Both offer viewing and editing on a video screen, hard copy printouts, and connection to the electrocardiograph via direct connect, removable diskette, or modem. Both systems feature a serial comparison function which shows waveform differences between successive ECGs.

An important difference is that TraceMaster does not perform any computerized interpretation of the ECG waveform.

9. Nonclinical Tests Used in Determination of Substantial Equivalence

The M1730B TraceMaster ECG System was tested for Electromagnetic Compatibility. Immunity tests included IEC 801-2, IEC 801-3, and IEC801-4.

Emissions were tested to measure the emission of radio-frequency electromagnetic fields and conducted RFI on the mains in accordance with CISPR22:1993, class A.

The essential functions of the M1730B TraceMaster ECG System have been validated in extensive system testing and was found to meet all requirements specifications.

10. Conclusions From Nonclinical Testing

The testing of the M1730B TraceMaster ECG System demonstrates that the performance is substantially equivalent to a subset of the features in the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

FEB 19 1998

Mr. Steven A. Clarke
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K974420
Trade Name: M1730 TraceMaster ECG System
Regulatory Class: II (two)
Product Code: 74 DSH
Dated: November 20, 1997
Received: November 24, 1997

Dear Mr. Clarke:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

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: K974420

Device Name: Mi730 TraceMaster ECG System

Indications For Use:

The M1730B TraceMaster ECG System is a computer system 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 NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for PBT

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K974420

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

(Optional Format 1-2-96)