K974087

JUN 15 1998

CHAPTER 25: SUMMARY OF SAFETY AND EFFECTIVENESS

1.0 Manufacturer/Submitter

1.1 Name and Address

Hewlett-Packard
Cardiology Products Division
Medical Products Group
3000 Minuteman Road
Andover, MA 01810

1.2 Establishment Registration Number

1218950

1.3 Hewlett-Packard Manufacturing Site Address

Hewlett-Packard Medical Products (Quindao) LTD
188 Zhuzhou Rd., Laoshan District
Qingdao
266101 China

1.3.1 Manufacturing Site Establishment Registration Number

9680888

1.4 Sterilization Site

Does not apply.

1.5 Contact Persons

You may contact Ray Stelting at (978) 659-3445 or Rick Petersen at (978) 659-2213, or Chas Burr at (978) 659-2529

1.6 Date

10/28/97

2.0 Regulatory Information

2.1 References

510(k) Notifications:

- K951978, M1791A Acute Cardiac Ischemia-Time Insensitive Predictive Instrument (ACI-TIPI)
- K895520, PageWriter XLi M1700A and PageWriter XL M1701A
- K954980, PageWriter 200i M1770A and PageWriter 200 M1771A

2.2 Device Name, Trade Name

Proprietary: Model M1792A Thrombolytic Predictive Instrument

Trade: HP TPI Application

2.3 Products (Components) Included As Part Of This Device:

No accessories or additional components are included as part of the Model M1792A Thrombolytic Predictive Instrument device.

2.4 Device Classification

We are not aware of a classification for this device.

2.5 Performance Standard:

None established under section 514.

3.0 Description

3.1 What it is and intended use

HP TPI is an accessory software device that provides probability indices to aid the clinician deciding whether to administer thrombolytic therapy or to provide another avenue of treatment. HP TPI can only be installed in prescription host devices that meet the HP TPI interface and computing platform requirements.

HP TPI is intended to be used by clinicians treating patients diagnosed as having experienced a recent acute myocardial infarction.

In the USA, Federal law restricts HP TPI to sale by or on the order of a physician.
It is intended to be used in a professional health care facility.

It is not intended for home use.

3.2 How the Algorithm Works

The algorithm uses ECG measurement information from the host cardiograph machine along with patient data input by the operator as factors in the equation used to calculate risk indices. The computed indices and the input data are printed on each ECG report.

3.3 Indications for Use

The indications for use of the HP TPI software device are:

Physiological purpose: To aid the clinician deciding whether to administer thrombolytic therapy or to provide another avenue of treatment;

Condition: Patient is a potential candidate for thrombolytic therapy;

Patient Population: adult (35 to 75 years) patients diagnosed as having symptoms of Acute Myocardial Infarction;

Body or type of tissue interacted with: No body or tissue contact;

Prescription versus over-the-counter: HP TPI is a prescription device.

4.0 Verification and Validation

Verification and validation shows that (1) HP TPI software operates properly with no known safety related defects when executing on qualified computing platforms, (2) the algorithm embodied in the software performs the same as the algorithm used during clinical testing, (3) identified hazards have been mitigated, and (4) that the host cardiograph performance has not been compromised by the installation of the HP TPI application software.

5.0 Safe and Effective When Used as Labeled

Documented test results obtained from extensive testing coupled with detailed user documentation of HP TPI and host devices produces a very high confidence level that the device is safe and effective when used as intended.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 15 1998

Mr. Ray Stelting
Hewlett-Packing Company
Medical Products Group
3000 Minuteman Road
Andover, MA 01810

Re: K974087
Model M1792A Thrombolytic Predictive Instrument
Regulatory Class: III (three)
Product Code: 74 LOS
Dated: October 28, 1997
Received: October 29, 1997

Dear Mr. Stelting:

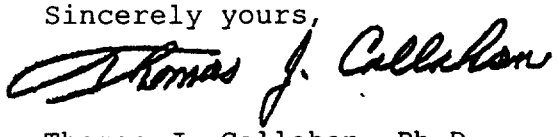
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K974087

Device Name: Model M1792A Thrombolytic Predictive Instrument

Indications For Use:

Indications for Use: Physiological purpose: To aid the clinician deciding whether to administer thrombolytic therapy or to provide another avenue of treatment; Condition: Patient is a potential candidate for thrombolytic therapy; Patient Population: adult (35 to 75 years) patients diagnosed as having symptoms of Acute Myocardial Infarction; Body or type of tissue interacted with: No body or tissue contact; Prescription versus over-the-counter: HP TPI is a prescription device.

Contraindications: "NOTE: The Thrombolytic Predictive Instrument (TPI) is contraindicated for patients with conditions that mimic acute myocardial infarction. Some of these conditions are: Prinzmetal variant angina, acute pericarditis, acute myocarditis, cardiomyopathy, and primary and secondary cardiac neoplasms.

The Thrombolytic Predictive Instrument (TPI) is also contraindicated for patients with conditions for whom the administration of thrombolytics is contraindicated. Some of these conditions are: aortic dissection, acute myocardial infarction due to bacterial endocarditis, vasculitis, intracardiac thrombi, and acute nonsuppurative and suppurative pericarditis mimicking acute myocardial infarction.

These situations, as well as Posterior Acute Myocardial Infarction, were not considered or covered in the development of the predictive instrument calculations."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Louis M Modoo 6-9-98 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 _____