

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
FOR
HEWLETT-PACKARD COMPANY**

**PAGEWRITER 200i INTERPRETIVE CARDIOGRAPH
MODEL M1770A
with
ACUTE CARDIAC ISCHEMIA
TIME INSENSITIVE PREDICTIVE INSTRUMENT APPLICATION
MODEL M1791A**

1. DATE SUMMARY PREPARED

April 2, 1998

2. SUBMITTER'S NAME AND ADDRESS

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

3. CONTACT PERSON

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4. DEVICE NAME

Proprietary Name: PageWriter 200i Model M1770A Interpretive Cardiograph
with Acute Cardiac Ischemia Time Insensitive Predictive
Instrument (ACI-TIPI) Model M1791A Application.

Common Name: Cardiograph

Classification Name: Electrocardiograph

5. PREDICATE DEVICES

The legally marketed devices to which equivalence is being claimed are listed below.

<u>Manufacturer</u>	<u>Predicate Device</u>	<u>Model</u>	<u>510(k) Number</u>
Hewlett-Packard	PageWriter XLi	M1700A with M1791A	K951978
Hewlett-Packard	PageWriter 200i	M1770A	K935772

The interpretative cardiographic functions of the PageWriter 200i Model M1770A with ACI-TIPI Model M1791A are identical to the predicate PageWriter 200i Model M1770A (K935772). The optional software application, acute cardiac ischemia time insensitive predictive instrument (ACI-TIPI) Model M1791A, is identical to the ACI-TIPI application that is commercially available for use with the predicate PageWriter XLi Model M1700A (K951978).

6. DEVICE DESCRIPTION

The ACI-TIPI Model M1791A is an optional software application for the commercially available predicate PageWriter 200i M1770A interpretive cardiograph. This optional software application is used to provide the cardiologist with an additional tool to aid in the assessment of acute cardiac ischemia. The ACI-TIPI application regression formula for ACI combines patient data (age, sex, and chest pain status) with measurements from the ECG. The computation yields a probability index of acute cardiac ischemia in the range of 0-100%. This index is intended to be used with the currently established data in evaluation of the subject patient population. As an index, the physician can correlate values with their current diagnostic results and then use the index to support their diagnosis, or to initiate further action. For example, the physician can use the index as part of the diagnostic data set used to assess a patient. This index is never used alone or in place of other pertinent information normally used in acute ischemia determinations.

7. INTENDED USE

The intended use of the PageWriter 200i Model M1770A with ACI-TIPI Model M1791A is similar to the intended use of the predicate PageWriter 200i Model

M1770A. They are both intended to be used for acquisition, digitization, recording of conventional diagnostic 12 simultaneous lead ECG waveforms and ECG data, and measuring and interpreting ECGs. In addition, the PageWriter 200i Model M1770A with ACI-TIPI Model M1791A has the same intended use as the predicate PageWriter XLi Model M1700A with ACI-TIPI Model M1791A. Specifically, they both are intended to provide a tool to aid in assessment of acute cardiac ischemia by correlation of the patient demographics, symptoms and ECG measurements.

8. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The PageWriter 200i Model M1770A with ACI-TIPI Model M1791A has the same interpretive cardiograph characteristics as the predicate PageWriter 200i Model M1770A. For example, they both contain the same ECG measurements, adult and pediatric analysis programs, ECG basic controls, conventional 12 simultaneous lead ECGs and both have the same recording techniques. The PageWriter 200i Model M1770A with ACI-TIPI Model M1791A has the same predictive algorithm characteristics as the predicate PageWriter XLi Model M1700A with ACI-TIPI Model M1791A. In fact, the exact same ACI-TIPI Model M1791A application is used with both interpretive cardiographs. In addition, the same parameters are entered by the user (patient ID, name, age, gender, height, weight and presence of chest pain) and the same input parameters are needed for the predictive algorithm (ACI-TIPI).

9. NONCLINICAL TESTS USED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The safety of the PageWriter 200i Model M1770A with ACI-TIPI Model M1791A is already proven because the interpretive cardiograph which will host the ACI-TIPI algorithm is commercially available for market worldwide. In addition, the ACI-TIPI Model M1791A application is also commercially available on another Hewlett-Packard interpretive cardiograph. The ACI-TIPI Model M1791A application has been validated and system testing was performed to verify that the addition of the ACI-TIPI Model M1791A application did not adversely alter the functionality of the PageWriter 200i Model M1770A interpretive cardiograph.

10. CONCLUSIONS FROM NONCLINICAL TESTING

The addition of the ACI-TIPI Model M1791A application to the predicate PageWriter 200i Model M1770A interpretive cardiograph has been successfully completed and passed validation testing. In addition, system testing verified that the addition of the ACI-TIPI Model M1791A application does not affect the interpretive cardiograph functionalities of the host PageWriter 200i Model M1770A.



JUN 23 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Renee J. Thibeault
Associate Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K981265
Hwelett-Packard Page Writer 200I Model M1770A
with ACI-TIPI Model M1791A
Regulatory Class: III (three)
Product Code: LOS
Dated: April 2, 1998
Received: April 7, 1998

Dear Ms. Thibeault:

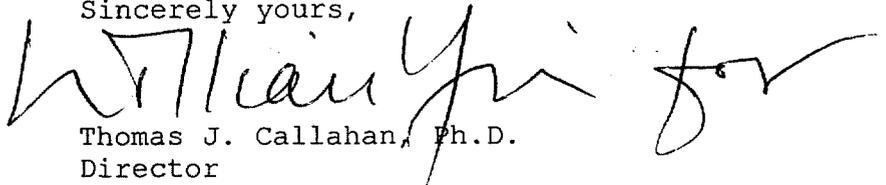
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (Pre-market 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): K981265

Device Name: Hewlett-Packard PageWriter 200i Model M1770A Interpretive Cardiograph with Acute Cardiac Ischemia Time Insensitive Predictive Instrument Application (ACI-TIPI) Model M1791A.

Indications For Use:

The PageWriter 200i Model 1770A is intended to provide acquisition, digitization and recording of conventional diagnostic 12 simultaneous lead ECG waveforms and ECG Data. The PageWriter 200i Model M1770A also displays ECG waveforms and records patient information entered through the alphanumeric keyboard. Additionally, it measures and provides interpretation. The PageWriter 200i Model M1770A interpreted ECG with measurements and diagnostic statements is offered to the physician on an advisory basis only, and the physician is asked to overread and validate (or change) the ECG interpretation.

In addition, the PageWriter 200i Model M1770A with ACI-TIPI Model M1791A is intended to provide the cardiologist with an additional tool to aid in assessment of acute cardiac ischemia.

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Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K981265

Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)