

JAN 20 2000

K993587

510(k) Summary.

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This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §.807.92.

1. The submitter of this premarket notification is:

Mike Hudon
Regulatory Approvals Engineer
Hewlett-Packard Company
Patient Monitoring Division
Healthcare Solutions Group
3000 Minuteman Road
Andover, MA 01810-1099
Tel.: (978) 659-3173
Fax.: (978) 687-2651

This summary was prepared on November 9, 1998.

2. The name of this device is the Hewlett Packard M2376A Device Link System. The common name is the HP Device Link. Classification is **Cardiovascular (74) MSX**, classification names for the externally connected devices are as follows:

REGULATION NUMBER	CLASSIFICATION NAME	PANEL	PROCEDURE CODE
870.1100	Alarm, blood pressure	Cardiovascular	74 DSJ
870.1110	Computer, blood pressure	Cardiovascular	74 DSK
870.1100	Alarm, blood pressure	Cardiovascular	74 DSJ
870.1130	System, measurement, blood pressure, noninvasive	Cardiovascular	74 DXN
870.2300	Monitor, cardiac	Cardiovascular	74 DRT
876.1800	Urinometer	Gastro-urology	78 EXS
876.5820	System, hemodialysis, access recirculation monitoring	Gastro-urology	78 MQS
880.5725	Pump, infusion	Gnr'l Hospital	80 FRN

3. The Hewlett Packard M2376A Device Link System receives digital data produced by external devices through device specific cables, converts that data into the HL7 format and transmits that information to any networked Clinical Information System.

4. When connected to a bedside device, the HP M2376A Device Link System is intended for electronic data collection and clinical information management. Device Link is neither patient connected, nor does it remotely control the attached source device.

**JAN 20 2000**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Mike Hudon
Senior Regulatory Affairs Engineer
Agilent Technologies, Inc.
Healthcare Solutions Group
3000 Minuteman Road
Andover, Massachusetts 01810-1099

Re: K993587
Trade Name: Agilent Technologies Device Link System
Model M2376A
Regulatory Class: II
Product Codes: MQS
Dated: October 22, 1999
Received: October 22, 1999

Dear Mr. Hudon:

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, 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 pre-market notification submission does not affect any

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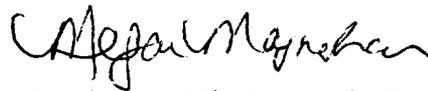
obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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) 594-4646. 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" (21CFR 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,

for



Celia M. Witten, Ph.D., M.D.
Acting Director
Division of Cardiovascular,
Respiratory and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993587

Device Name: Hewlett-Packard M2376A Device Link System

Indications for Use:

The M2376A Device Link System is indicated for use in data collection and clinical information management either connected directly or through networks with independent bedside devices.

The M2376A is not intended for monitoring purpose, nor is the M2376A intended to control any of the clinical devices (independent bedside devices / information systems) it is connected to.

 for DBT 1/18/00

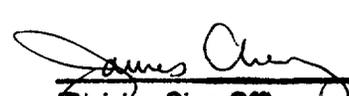
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use _____

(Optional Format 1-2-96)

 for DBT 1/21/00

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K993587