4/30/99

K984194

5.0 510(k) Summary.

510(k) Summary

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.

The name of this device is the Hewlett Packard M2376A DeviceLink System. The common name is the HP DeviceLink. Classification names are as follows:

REGULATION NUMBER	CLASSIFICATION NAME	PANEL	PROCODE
868.5895	Continuous ventilator	Anesthesiology	73 CBK
876.5820	System, hemodialysis, access recirculation monitoring	Gastro-urology	78 MQS
880.5725	Pump, infusion	Gnr'l Hospital	80 FRN

The above device is substantially equivalent to the HP M1032A VueLink Interface Plug-in Module marketed pursuant to K923682.

The Hewlett Packard M2376A DeviceLink 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.

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

The technological characteristics are the same or similar to those found with the predicate device, with the exception that neither waveforms, alarms, nor image data are transmitted in the DeviceLink System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 30 1999

Mr. Mike Hudon
Regulatory Affairs Engineer
Medical Products Group
Hewlett-Packard GmbH
Herrenberger Strasse 110-140
71034 Boeblingen GERMANY

Re: K984194
Hewlett-Packard Model M2376A Device Link System
Regulatory Class: II (two)
Product Code: MQS
Dated: March 11, 1999
Received: March 12, 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 (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" (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,

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 (if known): K984194

Device Name: Hewlett-Packard M2376A DeviceLink System

Indications for Use:

The HP M2376A Device Link System is indicated for use in data collection and clinical information management, either connected directly or through networks, with the independent bedside devices that are listed below:

1) IMED 1310 (PC-1) channel IV Pump
2) In-line Diagnostic HR Crit-Line Monitor
3) Newport Wave Ventilator

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K984194

Prescription Use ✓ **OR** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)