

A -- Executive Summary

Reason for Submission

The reason for this submission is to notify FDA that Hewlett-Packard plans to bring a new device , HP ORVue Intra-Op [M2510A] *Intraoperative Recording System* , to market.

This submission is to have Calculations of

- Fluid Balance
- Hemodynamic
- Renal
- Oxygenation
- Ventilation

as a Recording functionality in the HP ORVue Intra-Op [M2510A] software as one of the applications to support and enhance the clinical Intraoperative Recording (Anesthesia Protocol).

Until now Hewlett-Packard has determined the functionality of the HP ORVue Intra-Op [M2510A] to be exempt from reporting (based on exemptions described in FDA's guidance for computer controlled devices, see also Chapter "D. Description of the Device" part "Overview").

As a result this submission will primarily focus on the 'Recording of Calculations' functionality.

In terms of being a computerized system capable of accessing and displaying data coupled with Recording of the above described Calculations, this device is similar to the previously submitted CareVue 5000 system cleared to market under 510(k) number K922210 while the Calculations are identical to those of the market cleared devices Component Monitoring System Model HP M1175/76A [K922058] and Patient Monitor Model HP 78534C [K870380].

Description

The HP ORVue Intra-Op [M2510A] *Intraoperative Recording System* is a product that provides documentation of all anesthesia-relevant information, replacing parts (or all) of the paperchart of the anesthesia protocol in the operating theatre.

ORVue Intra-Op [M2510A] is easily adaptable to different types of anesthesia by means of multiple anesthesia-specific configurations designed to automate the charting process and address the needs of health care providers.

It is capable of providing the following six reports:

- * Anesthesia Report One Time
- * Anesthesia Report Continuous
- * Billing Report
- * QA Report
- * Graphics Report
- * Notes Report

whereas the anesthesia report contains the following information : Medication trends (Drugs/Gases and Infusions/Transfusions), Parameter trends, List of entries, IV/IA lines, Surgical information, Anesthesia information, Equipment used, Transfusions administered, Anesthesia times, Personnel involved, Discharge location, Summary of anesthesia, Post-op orders, Space for additional notes.

It is also capable of accessing data automatically from other HP and Non-HP devices/systems (such as Infusion pumps, computer systems (Database) and medical devices).

Validation

All of the processes for safe software development that were used to develop original device were followed and the software was fully validated.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

SEP 11 1997

Mr. Herbert van Dyk
Regulatory Affairs
Medical Products Group-Boeblingen
Hewlett-Packard GmbH
Schickardstrasse 4
D-71034 Boeblingen
GERMANY

Re: K965160
ORVue Intra-Op Intraoperative Recording System (M2510A)
Regulatory Class: II (two)
Product Code: 73 BSZ
Dated: June 13, 1997
Received: June 16, 1997

Dear Mr. Dyk:

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.

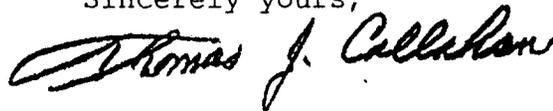
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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

Indications for Use

The HP ORVue Intra-Op [M2510A] Intraoperative Recording System is indicated for use in healthcare facilities by healthcare professionals whenever there is a need for an anesthesia record. This product is indicated for all patients requiring an anesthesia record. The specific medical indication for use of this device is:

- This device is a prescription device.
- This device is not intended to contact the patient.
- This device is used continuously in Operating Theatres during Anesthesia
- The Recording of calculations (Fluid, Hemodynamic, Renal, Oxygenation and Ventilation) indicated for any patient who will have medication administered and which requires dose computation.
- The physiological purpose is indirect. The device is intended to gather and store patient information during Anesthesia, and to document computed calculations as needed by care providers.



(Division Sign-Off)

Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number _____