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P -- [510(k)] Summary of Safety and Effectiveness

The Series 50 OB TraceVue is intended to replace the former HP Obstetrical Information Management System 80235B and M1370A. TraceVue combines the features of the former devices with the features of new PC technologies.
The HP Series 50 OB TraceVue allows easy-to-use patient surveillance in hospitals. It is easy to expand and the highly modular implementation offers antepartum and intrapartum alerting and optional storage.
The modular system approach of the HP Series 50 OB TraceVue offers the flexibility to build a **stand-alone** solution or to create complete **networks** that provide a monitoring and alerting solution for the entire OB department. It replaces traditional OBGYN paper Charts/Records with a configurable computerized version that has the capability to automatically gather data from various sources, enter the data, and then visually display the data in a comprehensive manner.
In addition it offers applications that support clinical decision-making, care management, Continuous Quality Improvement (CQI), and research.
The patient population includes those patients monitored on HP predicate devices.

The hardware for this system is off-the-shelf PCs and servers which meet the performance specification identified.

Description statements were mainly not relied on to show substantial equivalence to legally marketed devices; instead, performance data from device validation is used as well. The comparison of intended use and technological features of this device to other legally marketed devices taken together with validation results indicate that this device is substantially equivalent to legally marketed predicate devices with regards to safety effectiveness and intended use.

The safety of this PC device is shown by compliance to relevant safety standards for ITE devices such as UL 1950, IEC 950, EN 60950 for the hardware.
Software safety is verified by Hazard analysis and software validation to ensure the product performs as intended.

The electrical Safety requirements for the System as well as the compatibility requirements for the Interface Drivers have been carefully validated and successfull tested.
The results have proved that TraceVue meets these requirements.

The intended use of this device is the same as the intended use of many other products currently on the market. Specifically, there are HP Products as well as competitors products which are intended to provide the Obgyn Care provider this same information. Therefore, all aspect of this device have predicates which are well accepted in the clinical community.
This product simply provides more ready access to clinical information for the Obgyn Care provider.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 3 1997

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

Re: K970456
HP Series 50 OB TraceVue, Obstetrical
Surveillance and Archiving System
Dated: July 3, 1997
Received: July 7, 1997
Regulatory class: II
21 CFR §884.2740/Product code: 85 HGM

Dear Mr. van Dyk:

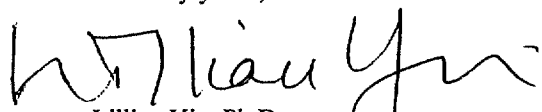
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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) 594-4613. 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,



Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

The HP Series 50 OB TraceVue is indicated for use in healthcare facilities by healthcare professionals whenever there is a need for comprehensive obstetrical surveillance of up to 30 patients at central station, all bedsides, nurses' lounges, physicians' lounges and offices.

The HP Series 50 OB TraceVue allows easy-to-use patient surveillance in hospitals. It is easy to expand and the highly modular implementation offers antepartum and intrapartum alerting and optional storage.

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 Obstetrical Departments

  Basic and advanced fetal trace alerting for both antepartum and intrapartum applications.

- The physiological purpose is indirect. The device is intended to gather and store fetal and maternal information during obstetrical period, and to document relevant information (surveillance) as needed by care providers.

Robert R Tallman

(Division Sign-Off)
Division of Reproductive, Abdominal, Ent,
and Radiological Devices

510(k) Number K970456

Prescription Use ✓
(Per 21 CFR 801.109)

Over-the-Counter Use _____