

8.0 510(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.

1. The submitter of this premarket notification is:

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Regulatory Affairs
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This summary was prepared on August 20, 1999.

2. The name of this device is the Hewlett-Packard Viridia Patient Monitor M3000A/M3046A with M3015A (Viridia M3/M4, Rel. B.). The common name is patient monitor. Classification names are as follows:

Regulation Number	Classification Name
870.2850	Extravascular Blood Pressure Transducer
870.1435	Computer, Diagnostic, Pre-Programmed, Single-Function
870.1400	Carbon Dioxide Gas Analyzer
870.1025	Detector and Alarm, Arrhythmia
870.2900	Cable, Transducer and Electrode, Patient (including connector)
868.1499	Carbon Dioxide Gas Analyzer
880.2910	Clinical Electronic Thermometer

3. The new combination device is substantially equivalent to previously cleared Nellcor Puritan Bennett™ NPB-75 and HP devices marketed pursuant to K964239, K981576 and K971910, respectively.

4. The modification is the addition of a firmware and software based change that involves the addition of the M3015A Module to the portable Viridia M3/M4 Patient Monitor System to allow sidestream CO2, and a second invasive blood pressure and temperature measurements with the unit.
5. The new device has the same intended use as the legally marketed predicate devices. When used in the hospital environment or mobile environment for patient transport monitoring, the device is intended for measuring and displaying, recording and alarming multiple physiological parameters and waves in adult, pediatric and neonatal patients.
6. The new combination device has the same technological characteristics as the legally marketed predicate devices.
7. Verification, validation and testing activities were conducted to establish the performance and reliability characteristics of the new module using simulated systems. Testing included system level tests, integration tests, environmental tests, safety testing from hazard analysis, interference testing, and hardware testing. Pass/Fail criteria were based on standards, where applicable, and on the specifications cleared for the predicate devices. The test results showed substantial equivalence.



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Mr. Egon Pfeil
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Re: K993383
HP Viridia Model M3015A Measurement Server Module
Regulatory Class: III (three)
Product Code: 74 DSI
Dated: January 10, 2000
Received: January 13, 2000

Dear Mr. Pfeil:

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.

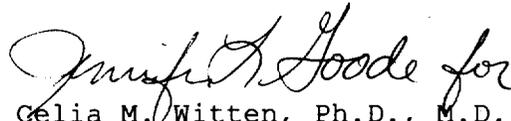
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. Egon Pfeil

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) 594-4645. 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/dsma/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
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Enclosure

