

DEC - 6 1999

K993907

9.0 510(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:

Dave Osborn
Regulatory Affairs Engineer
Healthcare Solutions Group
Agilent Technologies
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This summary was prepared on 10 November, 1999

2. The name of this device is the Viridia Information Software for Model M3154A Database Server, Release B.02. Classification names are as follows:

870.2800, II	74 DSH	Recorder, Magnetic Tape, Medical
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3. The new device is substantially equivalent to the previously cleared HP CentralVue Software device marketed pursuant to K964832, and K993171.
4. The modification is a software-based change that provides database server access via the hospital intra/internet system.
5. The new device has the same intended use as the legally marketed predicate device. It is used for the read-only viewing of patient physiologic data, including retrospective review applications of Alarm, Event, Wave, Trend, and ST segment (adults) Review to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms. The difference is that the modified device extends the review of retrospective patient data from the central monitor in the care unit to remote locations via the hospital's HIS LAN web access (hospital intra/internet).
6. The new device has the same technological characteristics as the legally marketed predicate device.

7. Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved system level tests, integration tests, environmental tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that web software interface functionality meets all reliability requirements and performance claims.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Dave Osborn
Regulatory Affairs
Agilent Technologies, Inc.
3000 Minuteman Rd.
Andover, MA 01810-1099

Re: K993907
Viridia Information Center (VIC) Software for Model M3154A
Database Server (DBS), Release B.02
Regulatory Class: III (three)
Product Code: MHX, DSI, MLD
Dated: November 16, 1999
Received: November 17, 1999

Dear Mr. Osborn:

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.

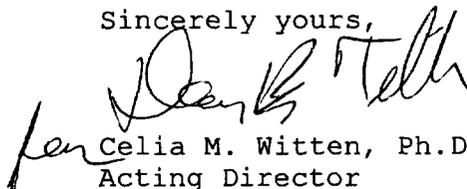
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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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,



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

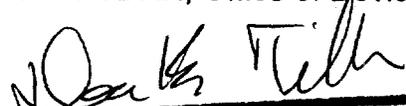
510(k) Number (if known): K993907

Device Name: Viridia Information Center (VIC) Software for Model M3154A Database Server (DBS), Release B.02

Indications For Use: For central monitoring of multiple adult, pediatric and neonatal patients; and where the clinician decides to monitor cardiac arrhythmia of adult, pediatric, and neonatal patients and/or ST segment of adult patients to gain information for treatment, to monitor adequacy of treatment, or to exclude causes of symptoms.

(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 K993907

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)