K003621

DEC 2 0 2000

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 CFR §807.92.

1. The submitter of this premarket notification is:

Dave Osborn
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Agilent Technologies
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This summary was prepared on 22 November, 2000

2. The name of this device is the Agilent Technologies ST/AR ST and Arrhythmia Software, Release D.0. Classification names are as follows:

870.1025, III	74 MLD	Monitor, ST Alarm
870.1025, III	74 DSI	Arrhythmia Detector and Alarm
None	74 MHX	Physiological Monitor, Patient Monitor

3. The new device is substantially equivalent to the previously cleared ST/AR ST and Arrhythmia Software device marketed pursuant to K964122, K991773, and K001348, as well as M2350/60A Component Central Monitor with Arrhythmia option, pursuant to K923747.

4. The modification is a software-based change that provides adjustable alarm limits for asystole and pause.

5. The new device has the same Indications for Use as the legally marketed predicate device. 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.

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, performance 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 ST/AR Release D meets all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2000

Mr. Dave Osborn
Agilent Technologies, Inc.
Healthcare Solutions Group
3000 Minuteman Road
Andover, MA 01810

Re: K003621
ST/AR, ST and Arrhythmia, Software Release D.0
Regulatory Class: III (three)
Product Code: 74 MHX
Dated: November 22, 2000
Received: November 24, 2000

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 (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/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K003621

Device Name: Agilent Technologies ST/AR Software, Release D.0.

Indications for Use: 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.

The intended use of the STAR cardiotach is to monitor a neonatal, pediatric, or adult patient's ECG for heart rate and produce events/alarms for one or two ECG leads. The cardiotach function is capable of monitoring both paced and non-paced patients.

The intended use of the STAR arrhythmia analysis algorithm is to monitor a neonatal, pediatric, or adult patient ECG's for heart rate and ventricular arrhythmias and produce events/alarms for one or two ECG leads. The arrhythmia analysis algorithm is capable of monitoring both paced and non-paced patients.

The intended use of the ST/AR ST analysis algorithm is to monitor an adult patient's ECG for ST segment elevation or depression and produce events/alarms for all possible ECG leads. The ST analysis algorithm is capable of monitoring paced and non-paced adult patients.

Note: The ST algorithm does not analyze ventricularly paced or ventricular ectopic beats.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use**

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

for Division of Cardiovascular & Respiratory Devices
510(k) Number K003621