

OCT 5 1998



1255 Kennestone Circle
Marietta, Georgia
30066-6029 USA

510(k) SUMMARY

K982550

**Establishment
Registration Number:** 1040777

Submitter: Betsy Cortelloni
Respironics, Inc.
1255 Kennestone Circle
Marietta, GA 30066
Phone: 770-429-2894
Fax: 770-499-1139

Date Prepared: July 20, 1998

Name of Contact: Betsy Cortelloni, Regulatory Affairs Associate

Device Name: Browser

Device Model Number: 4500E

Classification Name: Breathing Frequency Monitor, 21 CFR 868.2375

Device Classification: Class II

Predicate Devices: Healthydyne Technologies, Inc. 9500E software. Originally cleared under K892006 (5/23/89), and a subsequent modification K903287 (8/17/90).

Device Description: Browser is a Windows 95 software program used for reviewing events recorded by a Healthydyne Technologies SmartMonitor. Browser allows the operator to observe the time and duration of physiological events such as apnea, bradycardia, tachycardia and oxygen desaturation. The operator can also observe the waveforms associated with these events. These events and waveforms are downloaded from the monitor using a directly connected cable or via a modem.

510(k) Summary, continued:

Intended Use: Browser is a software program which is used by Healthcare Professionals to view, analyze and edit patient data gathered with a SmartMonitor® Infant Apnea Monitor.

Comparison of Technological Characteristics:

The predecessor to Browser is the Healthdyne Technologies 9500SE software. Since both software packages interface to the SmartMonitor, they both have the same essential user features. Both allow the user to observe physiological events and equipment events and both allow the user to view waveforms associated with events.

Browser runs on the Windows 95 platform whereas the 9500E ran on the DOS platform. However, Browser is not a port of the 9500E software to Windows. Browser is a completely new program that shares no source code with the 9500E.

Non-Clinical Testing:

The Browser Software Test Plan consisted of system level and module/integration level testing to verify all the defined software requirements. The tests utilized actual patient data as well as simulated patient data.

A clinical comparison of actual patient data was performed by comparing reports generated by the predicate 9500E software and the Browser software.

Conclusion:

The cumulative test results demonstrated the functionality and safety and effectiveness of the Browser software, as well as its substantial equivalence to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 5 1998

Ms. Betsy Cortelloni
Respironics, Inc.
1255 Kennestone Circle
Marietta, GA 30066

Re: K982550
Browser (Event Software) Model 4500E
Regulatory Class: II (two)
Product Code: 73 BZQ
Dated: July 21, 1998
Received: July 22, 1998

Dear Ms. Cortelloni:

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.

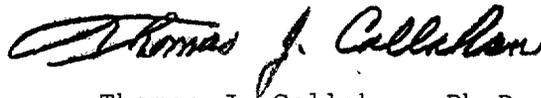
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992550

Device Name: BROWSER

Indications for Use:

Browser is a software program that is used by a HCP (Healthcare Professional) to view, analyze, and edit patient data gathered with a SmartMonitor® Infant Apnea Monitor.

Information that is collected includes patient information, equipment parameters, compliance logs, patient events, equipment events, and waveforms.

The data is downloaded to a PC, either by direct connection to the monitor or by modem. The data can also be retrieved from a computer file or memory disk such as a floppy or card.

The software allows the user to review and manipulate event information, produce reports, save changes, and forward data via e-mail.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark Kramer

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K98 2550

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)