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K964543

510(k) Summary

Submitter's Name: Nellcor Puritan Bennett Inc.

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Trade Name: Trending Option for the Infrasonics Adult Star Ventilator

Common Name: Adult Ventilator

Classification: Continuous Ventilator (21 CFR 868.5895)
Class II

Predicate Device: Puritan Bennett Graphics 2.0 option for the Puritan-Bennett 7200[®]ae ventilator
Bird Products Corp. Graphic Monitor

Description of Device: Trending Option is a software and hardware modification to the Adult Star Ventilator (K872466). It adds three features: 72 hour trending of ventilator and patient monitored parameters, storage of Patient Data, and Save and Recall of real time waveforms. This option requires both software and hardware upgrades. The software, or firmware, is retained in EPROM's. The hardware upgrade consists of a print circuit board with battery backed up 256K RAM. A label is added to the front of the ventilator indicating that this option has been installed. This option is designed to function with all available options for the Adult Star Ventilator.

Intended Use: This product is to be used only in conjunction with the Adult Star Model ventilator. It provides a monitoring function only and therefore has no direct interaction with ventilator function. The Trending option will periodically sample ventilator data to be used as trended parameters. This option is intended for the operator to track a total of 54 patient and ventilator parameters over a maximum time period of 72 hours. Three trended parameters can be displayed simultaneously. A cursor can then be used scan the trended dated to determine the time and magnitude of a particular occurrence or change in a monitored function. In addition, Patient data such as name, weight, clinician

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identification, and blood gas test data can be manually inputted. The Trending option allows real-time pressure, flow, and volume waveforms to be saved and recalled for comparison to subsequent waveforms. Pressure/Volume and Flow/Volume loops can also be saved and recalled for subsequent comparisons. A hardcopy print out can be made of all saved and trended data.

Statement of Similarities and/or Differences With Marketed Devices:

The Infrasonics Trending option is a software and hardware upgrade to the Infrasonics Adult Star ventilator. The graphical display of trended parameters are shown on the existing Adult Star CRT. The Trending option is similar to the Puritan Bennett Graphics 2.0 option and the Bird Products Graphics Monitor. The Puritan Bennett Graphics 2.0 option requires a 7200[®]ae ventilator and an optional 7202 Display. The Bird Graphics monitor is an optional display for the Bird infant and adult ventilators. The Puritan Bennett and the Bird Graphics monitor acquire and display data in a similar manner as the Infrasonics Trending option. All designs use the same general principles and incorporate similar technologies, materials, energy sources, and components.

The primary function of all three products is to acquire ventilator data through an electronic means and store that data for later retrieval. The technological characteristics of the devices are the same and raise no new questions of safety and effectiveness. It is concluded that the Trending Option is substantially equivalent to the Puritan-Bennett and Bird products.

Functionality with Available Options

The Trending Option for the Adult Star Ventilator is to be used in conjunction with or without other available options. The following is a list of the options and the 510(k) number associated with them:

Product or Option to the Adult Star	510(k) number
Adult Star Ventilator	K872466
Pressure Control	K911804
Flow Triggering	K954724
Remote Alarm	K943106
Lung Mechanics	K905272
Pediatric and Compliance Compensations	K922654

It is possible, for example, for a ventilator to be configured with Trending and Pressure Control, or Trending, Pressure Control, and Flow Triggering. System testing was conducted to show the There is no limitation on the combinations that are available. The Trending option is independent of the other options.

Summary of Testing:

The following environmental test were conducted on the Adult Star Ventilator with the Trending Hardware installed.

Test Description	Results
Powerline Conducted Emissions	Passed
Radiated Emission Measurements	Passed
Radiated E-Field Susceptibility	Passed
Electrostatic Discharge Susceptibility	Passed
AC Voltage Fluctuation	Passed
AC Voltage Dropout	Passed
Slow Sag and Surges	Passed
Fast Transient Burst	Passed
Fast Surges	Passed
Magnetic Fields Emissions	Passed
Conducted Electromagnetic Energy	Passed
Magnetic Field Immunity	Passed
Quasi-Static Electromagnetic Field	Passed
Sinusoidal Vibration	Passed
Random Vibration	Passed
Shock	Passed
High temperature	Passed
Low Temperature	Passed
Humidity	Passed

System Level Tests

The following system level tests were performed to validation the design of this option:

Test	Description
Design Validation for the Trending Option	Validates that the Design and Performance Specification has been correctly implemented.
Design Validation of Options Selection	Verifies that all available options for the Adult Star can be correctly selected.
Generic Testing (Includes specific testing for all available options:	A regression level to verify that function of the basic ventilator and available options still perform as required with the Trending Option Installed.