

PREMARKET NOTIFICATION [510(k)] SUMMARY
JUNE 20, 1996

K962473

VitalCom Contact Person: Mr. Ray Pizinger or Ms. Penni Pannell

Trade Name: VCOM Central Monitoring Station
V-PAK and V-LINK Transmitters
Arrhythmia and ST Segment

Common Name: Central Monitoring Station
Transmitters and Receivers
Arrhythmia and ST Segment

Classification Name: Monitors, Electrocardiographic
Transmitters and Receivers, Physiological Signal, Radiofrequency
Arrhythmia and ST Segment

Substantially Equivalent to: VCOM Central Monitoring Station (K942147)
V-PAK and V-LINK Transmitters (K942147)
Arrhythmia and ST Segment (K942147)

SUMMARY**INTENDED USE****1.1.1. PURPOSE AND FUNCTION OF VERSION 8.0 SOFTWARE RELEASE**

The purpose of this premarket notification is to expand the use of this device to also include patient monitoring using the V-Link transmitters connected to ventilators that have digital outputs that conform to either the Digital Communications Interface (DCI of the 7200 series ventilators) or the V-Link Host Protocol. Like the predicate V-Link transmitter, the V-Link with the Host Protocol (Generic V-Link) will also transmit the physiological parameters of the bedside monitors. The predicate device and this expanded intended use (ventilators) will continue to receive, display, monitor, store and distribute patient data and alarms to clinical personnel utilizing VitalCom's LAN technology. Options will still include Arrhythmia detection and alarms, ST Segment and Full Disclosure (history).

As with the predicate device, the physiological parameters, data and alarms are all controlled by the VCOM software. The physiological parameter set defined by the VCOM software has been updated to include the ventilator parameters. As with the predicate device, the distribution of the physiological parameters, data and alarms is controlled by the VCOM software and VitalCom's LAN technology. The V-Link software is also being updated to be capable of transmitting these new ventilator parameters.

The typical VCOM monitors up to ten patients using either ambulatory ECG transmitters (V-Pak) or radio transmitters (V-Link) connected to bedside monitors or ventilators. The VitalCom Networked Monitoring™ system may include interactive remote viewing stations (IRVS), and remote viewing stations (RVS) or VCOMs linked using the VitalCom wide area network (WAN) technology (Site-Link). As with the predicate device, multiple central stations (VCOM Hubs) maybe used in the clinical setting and connected via a local area network (LAN).

In summary the new intended use is adding the capability of the VitalCom Networked Monitoring™ system to connect to ventilators and receive, display, monitor, store and distribute patient data and alarms throughout the VCOM network.

1.1.2. INTENDED PATIENT POPULATION

As with the predicate device, the VitalCom Networked Monitoring™ system's ECG and Arrhythmia with ST Segment monitoring capabilities is intended to be used to monitor the adult patient population.

The VitalCom V-Link ventilator connection, is intended to be used to monitor those patients being ventilated by the predicate Puritan-Bennett 7200 series ventilator.

As with the predicate device, the VitalCom Generic V-Link with the Host Protocol is intended to be used to monitor those patients connected to the host device, either bedside monitors or ventilators.

1.1.3. INTENDED ENVIRONMENT OF USE

As with the predicate device, the VitalCom Networked Monitoring™ system and it's associated transmitters are intended to be used in an environmentally controlled clinical setting that has multiple patients using any combination of ECG leads, bedside monitors, or ventilator.

1.1.4. VERSION 8.0 SOFTWARE RELEASE CLAIMS

- a) As with the predicate device, the VitalCom Networked Monitoring™ system and it's associated transmitters are intended to be used in an environmentally controlled clinical setting that has multiple patients using any combination of ECG leads, bedside monitors, or ventilator.
- b) As with the predicate device, the VitalCom Networked Monitoring™ system is designed to provide an ongoing, real-time patient monitoring and alarm generation for changes in physiological parameters. When observed on the system or alerted by the system, the clinician can determine whether the event causing the change requires further clinical intervention.
- c) Users of existing VitalCom Networked Monitoring™ systems can option to upgrade their system, to be able to receive, display, monitor, store and distribute patient data and alarms from ventilators.

- d) The Generic V-Link is designed to transmit the VCOM's physiological parameters from other manufacturers devices, whose RS232 digital output has been configured to conform to the V-Link Host Protocol.
- e) VitalCom Networked Monitoring™ systems can be configured to allow multiple VCOM Hubs to share and overview patients' data.
- f) VitalCom Networked Monitoring™ systems can be configured to serve as the common backbone or data repository for physiological information within the VCOM network.
- g) The intended use of the VitalCom wide area network (WAN) connection is to communicate patient data between VitalCom devices utilizing the same Ethernet IEEE 802.3 protocols used in the predicate LAN network. This is intended to provide the means for clinicians from a primary or tertiary care hospital to assist the medical staff at the point of care hospital to over read and interpret physiological waveforms and patient data.

COMPARISON MATRIX

PCI Model 1100 vs. Expanded Features

Characteristic	PCI Model 1100 (K942147)		Expanded Features	
Display	14" and 17" color analog, RGB high resolution CRT		15" and 17" color analog, RGB high resolution CRT	
Physical	Mini-tower personal computer 486 or higher.		Mini-tower personal computer Pentium or higher.	
Channels	8 independent with 2 waveforms per channel. (16 for remote displays)		8 independent with 2 waveforms per channel. (16 for remote displays)	
Network	LAN Connections		LAN and WAN Connections	
Display Modes	Up to 8 channels full screen; up to 8 channels compressed to top half of screen with lower half dedicated to detailed patient view screens or control functions.		Up to 8 channels full screen; up to 8 channels compressed to top half of screen with lower half dedicated to detailed patient view screens or control functions.	
Waveforms	ECG		ECG	
	Pressure (IBP)		Pressure (IBP)	
	Pleth		Pleth	
	CO ₂		CO ₂	
	Resp.		Resp.	
Measurement Options from Bedside Monitors via Hardwire Connection or Telemetry (Radio Link)		<u>Alarms</u>		<u>Alarms</u>
	Heart Rate	Hi - Lo	Heart Rate	Hi - Lo
	NIBP	Hi - Lo	NIBP	Hi - Lo
	Systolic NIBP	Hi - Lo	Systolic NIBP	Hi - Lo
	Mean NIBP	Hi - Lo	Mean NIBP	Hi - Lo
	Diastolic NIBP	Hi - Lo	Diastolic NIBP	Hi - Lo
	NIBP Pulse Rate	Hi - Lo	NIBP Pulse Rate	Hi - Lo
	Systolic IBP	Hi - Lo	Systolic IBP	Hi - Lo
	Mean IBP	Hi - Lo	Mean IBP	Hi - Lo
	Diastolic IBP	Hi - Lo	Diastolic IBP	Hi - Lo
	IBP Pulse Rate	Hi - Lo	IBP Pulse Rate	Hi - Lo
	SpO ₂	Hi - Lo	SpO ₂	Hi - Lo
	SpO ₂ Pulse Rate	Hi - Lo	SpO ₂ Pulse Rate	Hi - Lo
	end tidal CO ₂	Hi - Lo	end tidal CO ₂	Hi - Lo
	inspired CO ₂	Hi - Lo	inspired CO ₂	Hi - Lo
Respirations	Hi - Lo	Respirations	Hi - Lo	
Temperatures	Hi - Lo	Temperatures	Hi - Lo	
Messages	Status Messages		Status Messages	
System Alarms	Nurse Alarm		Nurse Alarm	
	Lead Off Alarm		Lead Off Alarm	
	Low Battery		Low Battery	

COMPARISON MATRIX

PCI Model 1100 vs. Expanded Features

Characteristic	PCI Model 1100 (K942147)	Expanded Features	
System Alarms	Muscle	Muscle	
	No Signal	No Signal	
	Wrong ID	Wrong ID	
	Edit	Edit	
			Check Patient
Trends	Graphic trends of all parameters.	Graphic trends of all parameters.	
Recorder (Optional)	Dual channel, thermal array.	Dual channel, thermal array.	
Arrhythmia (Optional)	Red prompt and audible alarm for asystole, ventricular fibrillation, ventricular tachycardia. User selectable response for Ventricular Rhythm, Run PVC's, Salvo PVC's, Ventricular Bigeminy, Ventricular Trigeminy, Couplet, Triplet, Supraventricular Tachycardia.	Red prompt and audible alarm for asystole, ventricular fibrillation, ventricular tachycardia. User selectable response for Ventricular Rhythm, Run PVC's, Salvo PVC's, Ventricular Bigeminy, Ventricular Trigeminy, Couplet, Triplet, Supraventricular Tachycardia.	
ST Analysis (Optional)	User selectable ST alarm on ST elevation or depression.	User selectable ST alarm on ST elevation or depression.	
Full Disclosure (Optional)	All data for 8 patients.	All data for 8 patients.	
Hard Wire (Optional)	Serial Port RS 232	Serial Port RS 232	
	Serial Port RS 422	Serial Port RS 422	
Telemetry (Optional)	FCC approved and digital encoded FM-FSK technique at 174 - 216 MHz or 902 - 928 MHz frequencies.	FCC approved and digital encoded FM-FSK technique at 174 - 216 MHz or 902 - 928 MHz or other FCC approved frequency bands for medical telemetry.	
V-Link Transmitter (Optional)	FCC approved and digital encoded FM-FSK technique at 174 - 216 MHz., compatible with specific Bedside Monitors.	FCC approved and digital encoded FM-FSK technique at 174 - 216 MHz or other FCC approved frequency bands, compatible with specific Bedside Monitors and Ventilators.	
Measurement Options from Ventilators via V-Link Transmitter		<u>Ventilator Settings</u> Tidal Volume Setting	<u>Alarms</u> Lo Exh.
		Respiratory Rate	Hi
		Peak Flow	---
		Mode	---
		Oxygen %	---
		Plateau	---
		Sensitivity	---

COMPARISON MATRIX

PCI Model 1100 vs. Expanded Features

Characteristic	PCI Model 1100 (K942147)	Expanded Features	
Measurement Options from Ventilators via V-Link Transmitter		<u>Ventilator Settings</u> PEEP/CPAP	<u>Alarms</u> Lo
		Support Pressure	---
		Waveform	---
		Automatic Sigh	---
		I:E Ratio	Hi
		Minute Volume	Lo Exh.
		Spont. Min. Volume	---
		Peak Airway Pressure	Hi
		Mean Airway Pressure	---
		Plateau Pressure	---
		Inspiratory Pressure	Lo
		Inspiratory Time	---
		Nebulizer Status	---
		100% O ₂ Suction	---
		Sigh Volume	---
		Sigh HP Limit	Hi
		Sigh Rate	---
		Multiple Sighs	---
		SPO ₂	Hi-Lo
		Pulse Rate	Hi-Lo
	Airway Pressure Disconnect	Alarm	
	Apnea	Alarm	
Status Messages		Alarm Silence	
		Exhalation Valve Leak	
		Low Pressure Air Inlet	
		Low Pressure O ₂ Inlet	
		Safety Valve Open	
		Apnea Ventilation	
		Plateau Time	
		Inhaled Tidal Volume	
	Compliance		

TECHNOLOGICAL CHARACTERISTIC REVIEW

The VitalCom Networked Monitoring™ system with the expanded intended use is substantially equivalent to the **VitalCom MPC 1100 (K942147)** and, for use with ventilators, **Spacelabs' PCMS Monitor, Model 90845 (K913038) with Flexport Interface (K903702)**. The VCOM uses a pentium based personal computer and offers a wireless interface (radio transmitters and receivers). This technology is equivalent to the 486 based personal computer and are exactly the same transmitters and receivers contained in the **VitalCom MPC 1100 (K942147)**.

NON-CLINICAL PERFORMANCE DATA REVIEW

The determination of substantial equivalence was based on an assessment of non-clinical performance data. The data includes testing for EMI compatibility and susceptibility, software verification and validation of both the system software performance as well as the operating system software performance, environmental testing and stress testing both at the integration level and the system level. The conclusion drawn from a review of the data indicates that the VitalCom Networked Monitoring™ system, 7200 Ventilator V-Link, and Generic V-Link are substantially equivalent to the predicate devices.

CLINICAL PERFORMANCE DATA REVIEW

The determination of substantial equivalence was also based on an assessment of clinical performance data, which was provided in summary format for the study conducted between St. Mark's Hospital and Allen Memorial Hospital.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 6 1997

Mr. Raymond M. Pizinger
Vitalcom Inc.
15222 Del Amo Avenue
Tustin, California 92680

Re: K962473
VitalCom Networked Monitoring™ System
Regulatory Class: III (three)
Product Code: 74 MSX
Dated: August 15, 1997
Received: August 18, 1997

Dear Mr. Pizinger:

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 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" (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/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): K962473

Device Name: VitalCom Networked Monitoring™ System

Indications for Use:

The indications for use of the VitalCom Networked Monitoring™ system (VCOM, IRVS/RVS) are:

Monitoring of Recognized Conditions

An environmentally controlled clinical settings that has multiple patients using any combination of ECG leads, bedside monitors or Nellcor Puritan Bennett (NPB) 7200 series ventilators.

Hospital areas that have the capability of installing hardwire paths to the VitalCom's Central Monitoring Station (VCOM) from the rooms or areas where bedside monitors or NPB 7200 series ventilators operate.

Clinical areas that have the capability of installing 174-216 MHz radio systems (or alternate frequency bands approved by the FCC) to communicate via RF. The information from the ECG leads, bedside monitors or NPB 7200 series ventilators is transferred via an RF transmitter to the Central Monitoring Station (VCOM).

The Target Population

Those patients who are connected through the VitalCom Networked Monitoring™ system via ambulatory ECG transmitters, bedside monitors or NPB 7200 series ventilators.

Important Limitations

Each VitalCom Network Monitoring™ system can monitor up to a maximum of 10 patients per Central Monitoring Station (VCOM) and 200 patients per VitalCom Networked Monitoring™ system.

The VitalCom Central Monitoring Station (VCOM) is to be installed at the point of care locations that have the capability of installing hardwire paths to a VCOM from rooms or areas where bedside monitors or NPB 7200 series ventilators operate.

If employing wide area networking technology, the communication between the VCOM, at the point of care location, and the IRVS/RVS, at the supplementary care location, is facilitated by dedicated telephone lines and commercially available interface hardware.

The VitalCom Networked Monitoring™ system is not for use in the home.

The Central Monitoring Station (VCOM), is only used at the point of care location and is capable of operating independently of any IRVS/RVS connections.

* Indicates changes made during the submission review.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy Truman for AAC

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

Intended Use Summary:

NOV - 6 1997

The intended use of VitalComs Networked Monitoring System is monitoring of adult (ambulatory and bedside) patients vital signs including ECG and Arrhythmia with ST Segment monitoring and Alarms (which is identical to its predicate system, K942147). The intended use of VitalCom Networked Monitoring System has been expanded to monitor those patients being ventilated by the predicate Nellcor Puritan-Bennett 7200 series ventilator or other compatible ventilators. For ventilator patients, the alarms are processed at and by the ventilator unit and the central monitor simply displays the alarms received from the ventilator. The VitalCom Central Monitoring Station (VCOM) is intended to be used with bedside monitors or ventilators, but will only recognize those devices that have been validated by VitalCom as compatible.

The VitalCom Networked Monitoring System is intended to be used within an environmentally-controlled hospital or clinical setting by qualified personnel who are acting on the orders of a physician and trained in the use of the equipment; in which, multiple central stations (VCOM hubs) are connected via a local area network (identical to its predicate system, K942147). The network communication has been expanded to provide the means for clinicians from a supplementary care (primary or tertiary care) hospital to assist the medical staff at the point of care hospital to over read and interpret physiological waveforms and patient data using VitalComs proprietary WAN (wide area network) technology (SiteLink). The VCOM is used only at the point of care location and is capable of operating independently of any IRVS (interactive remote view station) and RVS (remote view station) connections.

If employing SiteLink patient monitoring, the communication between the VCOM, at the point of care location, and the IRVS/RVS, at the supplementary care location, is facilitated by dedicated telephone lines and interface hardware with an established set of (*) policies and procedures between the two sites.

The primary responsibility for monitoring and care of the patients resides with the point of care facility. As with all monitors, the system cannot replace skilled nursing care and proper surveillance.

The VitalCom Networked Monitoring System is not intended for use in the home.

(*) SiteLink Operations Manual should include but not limited to the following information:

- timely emergency notification of personnel
- loss of WAN communications link between two sites (e.g., loss of phone line)
- admitting patients to be monitored
- temporary removal of patients from monitoring
- discharging patient from monitoring
- routine reporting of patient parameters