K052751

DEC 2 3 2005

PREMARKET NOTIFICATION 510(k) SUMMARY
As required by §807.92

Device Name – as required by 807.92(a)(2):

Trade Name:	**VentLink™ System VentLink is a Trade Mark of MediServe Information Systems, Tempe, AZ**
Common/Classification Name:	**Ventilator Data Management System/ Accessory To Continuous Ventilator (respirator)**
Classification Regulation:	**868.5895**
Device Class:	**Class II (accessory to)**
Product Code:	**MOD**
Panel:	**Anesthesiology**

Premarket Notification submitter:
MediServe Information Systems,
3225 South Hardy Drive, Ste. 101, Tempe, AZ 85282

Contact: Mark Ofori-Kyei, Director of Quality Assurance and Change Management

Preparation Date: 9/28/2005

A. LEGALLY MARKETED PREDICATE DEVICE – as required by 807.92(a)(3)

The **VentLink** device is substantially equivalent to the **Ventnet system, K963633, submitted by Puritan Bennett Corporation, Tustin, CA.**

B. DEVICE DESCRIPTION – as required by 807.92(a)(4)

The VentLink system is a device composed of MediServe Information Systems' proprietary software and various off-the-shelf hardware, operating system software and third-party proprietary software intended to be interfaced with specified or validated ventilator devices to allow authorized users to move ventilator patient data to wireless laptops and workstations configured with MediServe Information Systems' MediLinks data storage software[1]. Additionally, the VentLink system allows users to move ventilator data to the

[1] MediLinks data storage software is a Class I proprietary standalone software application of MediServe Information Systems, the submitter.

user's hospital information system (HIS). It is intended to be used in an environmentally controlled hospital and hospital type environment.

The VentLink system software allows users to:

- Enable or disable automatic device data collection.
- Set a default data collection time interval.
- Specify how long unauthenticated data will be retained.
- Alert the user when data collection is paused.

After user review and validation of results received via the Ethernet the results are stored short-term on the VentLink system and transmitted to MediLinks for acceptance and storage.

Specified or validated ventilator devices are interfaced and added to the VentLink system through VentLink's devices' dictionary.

The VentLink system does not alter or change any patient data, but does allow the user to display the received patient data.

VentLink will function within a wide array of connectivity modules which allow VentLink to adapt to the evolving connectivity technology.

VentLink also has advanced device-management functionality.

C. DEVICE CLAIMS - as required by 807.92(a)(4)

The VentLink™ system is an interface application for ventilator devices that runs as a service on a server. VentLink works in concert with MediLinks®, an integrated point-of-care application suite intended for managing clinical departmental information activities and tasks.

The VentLink service communicates via Ethernet with the ventilator devices that have been configured within MediLinks. The purpose of the VentLink service is to collect data from the designated ventilators at specific time intervals and store the data in a database utilized by MediLinks.

The VentLink service cannot be used without MediLinks. MediLinks provides the user interface to the VentLink service. A MediLinks user can enter new ventilators, set data collection intervals, create Patient – Ventilator associations, and review and authenticate ventilator data collected by the VentLink service. MediLinks allows the user to generate reports of monitored ventilator information and also provides means for archiving data.

MediLinks will be used as a Central Monitoring Station that will allow users to remotely review summary information from many different ventilators at a

glance. The system will also be configurable to page an appropriate user when certain events (e.g. alarms) occur.

D. PRODUCT AND TECHNICAL SPECIFICATIONS - as required by 807.92(a)(4)

The purpose of this section is to show recommended minimum specifications for the VentLink system. MediServe Information Systems does not supply any hardware. While specific requirements may vary from one customer to another, the specifications listed below provide general guidance in determining hardware and system software needed for VentLink.

Client/Server Workstations

Recommended
Workstations • Pentium4 2.8 GHz or higher • 80 GB Hard Disk or greater • 512 MB RAM or greater • Windows 2000 Professional SP4 or Windows XP Pro SP2 • 32-bit SVGA Graphics Card, 32 MB RAM • 1024x768 Display Resolution • SVGA Monitor (17") or greater • 100BaseT 32-bit PCI Network Card

Thin Client Workstations

Recommended
Workstations • Pentium4 2 GHz or higher • 40 GB Hard Disk or greater • 512 MB RAM or greater • Windows 2000 Professional SP4 or Windows XP Pro SP1 • Internet Explorer 6.0 or greater (with 128-bit encryption) • 32-bit SVGA Graphics Card, 32 MB RAM • 1024x768 Display Resolution • SVGA Monitor (17") or greater • 100BaseT 32-bit PCI Network Card

Note: Thin client devices can be used for thin client computing via Citrix MetaFrame and must include Internet Explorer 5.5 or greater and support Citrix ICA and NFuse clients.

Database Server (up to 1200-1500 procedures/day or up to 50 concurrent users)

Recommended
Database Server • Dual (2) Pentium4 2 GHz or greater • 3 GB RAM or greater • 4(+) x 36 GB Ultra 3/4 SCSI Hard Drives (RAID-5) • 32-bit Caching Array Controller 64 MB RAM or greater • 2 x 100BaseT 32-bit Network Card • Windows 2000 Server SP4 or Windows Server 2003 • Microsoft SQL Server 2000 Enterprise Ed. SP3 • Monitor, CD-ROM

Database Server (up to 2500+ procedures/day or up to 100 concurrent users)

Recommended
Database Server • Dual (2) Intel Xeon 3 GHz or greater. 4 processors for larger volume sites • 4 GB RAM or greater • 6(+) x 36 GB or 72 GB Ultra 3/4 SCSI Hard Drives (RAID-5 or RAID 10) • 32-bit Multi-Channel Caching Array Controller 128 MB RAM or greater (the array should be constructed using multiple I/O channels) with additional embedded 64MB controller for system drive • 2 x 100BaseT 32-bit Network Card • Windows 2000 Advanced Server SP4 or Windows Advanced Server 2003 • Microsoft SQL Server 2000 Enterprise Edition SP3 • Monitor, CD-ROM

Thin Client Server(s)

Recommended
Citrix MetaFrame Server (up to 30 users) • Dual (2) Xeon 2.8 GHz or greater • 3 GB RAM or greater (64 MB per concurrent user) • 3 x 36 GB Ultra 3/4 SCSI Hard Drives (RAID-5) or 2 x 72 GB Ultra 3/4 SCSI Hard Drives (RAID-1) • 32-bit Caching Array Controller 64 MB RAM or greater • 2 x 100BaseT 32-bit Network Card • Windows 2000 Server SP4 or Windows Server 2003 • Citrix MetaFrame v1.8 or XP (XPs, XPa, XPe) • Citirx Load Balancing is required for multiple servers • Monitor, CD-ROM

Interface Computers

Recommended
Interface Computer • Dual (2) Intel Xeon 2.4 GHz or greater • 3 GB RAM or greater • 2 x 72 GB Ultra 3/4 SCSI Hard Drives (RAID-1) • 32-bit Caching Array Controller 16 MB RAM or greater • 100BaseT 32-bit Network Card • Windows 2000 Server SP4 or Windows Server 2003 • Microsoft SQL Server 2000 Personal Edition SP3 • Monitor, CD-ROM

Network Environment

Recommended
Report Writing • Crystal Reports v11 Pro **Backup and Printing** • Laser Quality Printer • Uninterruptible Power Supply w/Monitoring Software (all servers) • Tape Backup Unit (DAT, DLT, etc.) w/Backup Software (e.g. ArcServe) **Cabling and Connectivity** • 100BaseT (100Mbps) Ethernet Multiport Hub or Switch • Category 5e Patch cabling (CAT5e) • Category 5e Facility cabling (CAT5e) **Remote Support** • Terminal Services or Symantec pcAnywhere to Database Server and Interface Computers • VPN Client connection via the Internet. **LAN/WAN Bandwidth Requirements** • 128Kbps per concurrent user (for Citrix: 32Kbps per concurrent user) **Wireless Requirements** • MediLinks must connect using Citrix MetaFrame. **ASP Requirements** • TCP/IP protocol support required • Host-to-Host or Client-Host VPN connections between MediServe ASP and facility are supported. Contact MediServe for details.

E. INTENDED USE - as required by 807.92(a)(5)

Intended use:

The **VentLink system** is intended for use with specified or validated ventilator devices to obtain ventilator data and provide the user with the ability to display, store, print and otherwise process that data to other interfaced systems.

VentLink is not connected directly to any patient nor does the **VentLink** device remotely control any connected ventilator device.

Indications For Use

The **VentLink system** is intended for use in any clinical setting while interfaced to any specified or validated ventilator device. The **VentLink system** is intended to provide a secondary display of data received from an interfaced ventilator device to appropriately configured workstations and wireless laptop computers and to be made available to any interfaced hospital information system (HIS).

F. TECHNOLOGICAL CHARACTERISTICS SUMMARY – as required by 807.92(a)(6)

The **VentLink** system has the same indications for use as the **Ventnet system, K963633**. The **VentLink system** has the same technological characteristics as the **Ventnet system**. **Section III Substantial Equivalence** of this submission provides a detailed **COMPARISON MATRIX** of the **VentLink system** to the predicate **Ventnet system**.

The submitter claims that the **VentLink system** is substantially equivalent to the predicate device, the **Ventnet system**.

The technological characteristics of the **VentLink system** are very similar to those of the **Ventnet system**. The differences include:

TABLE OF DIFFERENCES BETWEEN THE VENTLINK SYSTEM AND THE VENTNET SYSTEM

Characteristic	VentLink system	Ventnet system
Hardware	No hardware provided.	Solution includes hardware.
Computer hardware	Specified but not provided by user.	Solution includes computer hardware.
Computer Operating System	Specified but not provided by user.	Solution includes computer operating system.
Color Monitor	Specified but not provided by user.	Solution includes color monitor.

Radio Transmitter Interface (wireless)	Specified but not provided by user.	Solution includes radio transmitter interface.
Remote Transceiver	Not specified.	Solution includes remote transceiver.
Central Transceiver	Not specified.	Solution includes central transceiver.

The submitter concludes that the **VentLink system** employs the same type of technological characteristics including computer hardware, operating system(s), cabling, networking and similar functionality to the **Ventnet** system. The majority of differences relate to evolutionary changes in technology that has occurred since the release of the **Ventnet system**.

G. NON-CLINICAL PERFORMANCE DATA TESTING AND REVIEW - as required by 807.92(b)(1)

Since the submitter uses only off-the-shelf hardware components, only certifications provided by the manufacturers of those components were obtained to document that EMI compatibility and susceptibility meets acceptable industry levels. Those certifications are attached in **Exhibit 10 Component/Accessory Validation**.

The submitted device has undergone significant verification and validation testing. Alpha validation testing included testing of all functionality and confirmation that all identified hazards have been adequately addressed by software functionality, the user interface or documentation.

Alpha validation activities included specified system software and operating software performance and environmental testing within the specified environment.

Additionally, each specified ventilator system has been or will be fully validated by users in beta testing environments PRIOR to implementation to ensure that each specified or validated ventilator operating environment meets all appropriate specifications.

The submitter requires that any user of an un-validated specified or unspecified ventilator device perform a documented, successful, ventilator/**VentLink** validation prior to authorizing the user operate their system in a live environment. See **Section IV**, for a description of the User's Validation Protocol and **Exhibit 12 Users' Manual, Implementation Manual and Users' Validation Protocol** for a **User's Validation Protocol** provided to users of un-validated specified or unspecified ventilator devices.

The submitter's validation testing fully documents that specified ventilator device's data is transmitted from the ventilator through the **VentLink system** into

the submitter's **MediLinks device**[2] with user control of data review and acceptance. No changes were made to transmitted ventilator data.

In these regards, the **VentLink system** is similar to and substantially equivalent to the capabilities of the predicate device, the **Ventnet system**.

The predicate device, **Ventnet system**, did not provide or reference any clinical tests submitted in compliance with **807.92(b)(2)**, therefore the submitter believes such clinical testing is not appropriate or required by FDA and has not made or provided any summary of such testing.

[2] MediLinks is a Trade Mark of MediServe Information Systems, Tempe, AZ

H. CONCLUSIONS AND SUMMARY- as required by 807.92(b)(3) and (c)

The nonclinical testing, in the form of alpha and beta validation studies document that the **VentLink system** is

- Safe, and
- As effective as the predicate device, the **Ventnet system**, and
- Performs as well or better than the predicate device, the **Ventnet system**, and, is therefore,
- Substantially equivalent to the identified predicate device, the **Ventnet** system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2005

Mr. Mark Ofori-Kyei
Official Correspondent
Mediserve Information Systems, Incorporated
3225 Suoth Hardy Drive, Suite 101
Tempe, Arizona 85282

Re: K052751
Trade/Device Name: VentLink™ System
Regulation Number: 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: II
Product Code: MOD
Dated: September 30, 2005
Received: September 30, 2005

Dear Mr. Kyei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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.

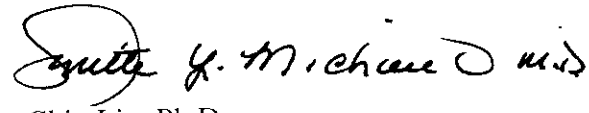
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
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Enclosure

INDICATIONS FOR USE

[510(k)] Number: **K052751**

Device Name: **VentLink™ system**

Indications For Use: The VentLink System is intended to be used in any clinical setting while interfaced to any specified or validated ventilator device. The VentLink system is intended to provide a secondary display of data received from an interfaced ventilator device to appropriately configured workstations and wireless laptop computers and to be made available to any interfaced hospital information system (HIS).

Prescription Use__✓__ AND/OR Over-the-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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