

K973640

TS2000 MEDICAL DEVICE MONITOR

Premarket Notification 510(k)

510 (K) SUMMARY

MAR 12 1998

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.929(c).

Submitter: Trincore Systems, Inc.
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Fort Worth, TX 76137-1413

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Email: trincore@juno.com

Contact Name: Vincent Occhipinti

Date Prepared: 15 September 1997

Common Name: Commonly Known as Central Monitoring Station Software.

Proprietary Name: TS2000 Medical Device Monitor (TS2000)

Classification: The TS2000 is Considered an Accessory to Type II Devices.

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Performance Standard: Performance standards (section 514 of the Act) have not yet been established for the device that is the subject of this premarket notification submission.

Device Description:

The TS2000 Medical Device Monitor is a PC based Central Monitoring Station that takes the information from different medical devices and redisplay them on a single monitor in a central location. It allows the remote monitoring of multiple medical devices simultaneously at the central station. The TS2000 provides secondary annunciation of the alarms from the medical devices at the central station as well.

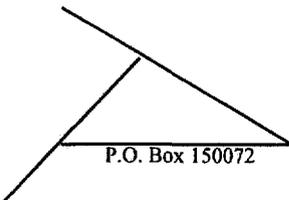
Intended Use:

The TS2000 is intended for use as an accessory to Type II medical devices, specifically pulse oximeters and infusion pumps.

It is intended for use by healthcare professionals trained in the use of the medical devices that are being monitored.

The TS2000 is intended for use with patient populations, being monitored by healthcare professionals, undergoing the use of these Type II medical devices.

The TS2000 is intended for use in locations, such as hospitals, outpatient clinics, free standing surgical centers or other locations that monitor these Type II medical devices.



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Predicate Devices: Baxter Flo-Gard 6301 Volumetric Infusion Pump (K915522)
Nelcor Puritan Bennett Oxinet II (K942147)

Comparison to Baxter Flo-Gard 6301 Volumetric Infusion Pump (K915522)

Local monitoring of this medical device is then available by viewing the display panel on the medical device and if desired, recording of the parameters. The TS2000 extends this concept by extending the display panel to a more centralized location.

By providing this remote viewing capability, the TS2000 provides additional assistance to the healthcare professional and makes the current local monitoring process safer and more effective in the following ways:

Provides additional assistance in the monitoring process

Safe and Effective

Reporting

Better management of medical devices

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Comparison to Nellcor Puritan Bennett Oxinet II (K942147)

<i>Characteristic</i>	<i>TS2000</i>	<i>Oxinet II</i>
<i>Computer</i>	Pentium Class PC	Pentium Class PC
<i>Display</i>	SVGA Color Monitor without Touchscreen	SVGA Color Monitor With Touchscreen
<i>Software Operating System</i>	MS Windows 95	Unknown
<i>Patient Capability</i>	over 40 Patients	up to 30 Patients
<i>Communications</i>	RS-232 (Hardwire)	Wireless 903-928 Mhz (Spread Spectrum Radio)
<i>Central Station</i>	Modular Multi Parameter	Modular Multi Parameter
<i>Devices Monitored</i>	Pulse Oximeters Infusion Pumps	Nellcor Symphony Monitors N-3000 Pulse Oximeter N-3100 Blood Pressure
<i>Data</i>	Continuous	Continuous
<i>Alarms</i>	Visual and Audible	Visual and Audible
<i>Reporting Capabilities</i>	Multiple Available	Multiple Available
<i>Calculations</i>	Provided by the Device	Provided by the Device
<i>Trends</i>	24 hours	24 hours
<i>Graphical User Interface</i>	Yes	Yes

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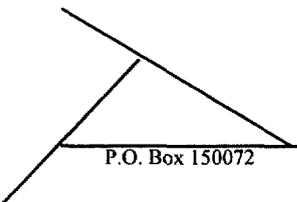
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Statement of Substantial Equivalence:

The TS2000 monitors bedside medical devices at a more central location and provides enhancements to the normal bedside monitoring procedure. Any differences between the predicate devices do not increase any risk to the patient or change the overall concept of a central monitoring station.

The TS2000 software has thoroughly been validated for safety or effectiveness by complying with the requirements of the *Reviewer's Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review*. Other guides that were referenced were the *Software Development Activities* and the *General Principles of Software Validation*. Non-clinical tests were conducted using both bench and simulation testing according to the test phase defined by the TS2000 Software Life Cycle.

Trincore Systems feels that the TS2000 is substantially equivalent to the predicate devices and other legally marketed central monitoring stations.

The logo for Trincore Systems, Inc. is a stylized triangle formed by three lines. One line is horizontal at the bottom, another is vertical on the left side, and the third is diagonal, connecting the top of the vertical line to the right end of the horizontal line.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Mr. Vincent Occhipinti
President
Trincore System, Inc.
7409 Butternut Court
Fort Worth, TX 76137-1413

MAR 12 1998

Re: K973640
TS2000 Medical Device Monitor
Regulatory Class: Unclassified
Product Code: 74 MSX
Dated: February 12, 1998
Received: February 17, 1998

Dear Mr. Occhipinti:

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 (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 requirement, 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 - Mr. Occhipint

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): K973640

Device name: TS2000 Medical Device Monitor

Indications For Use:

The TS2000 Medical Device Monitor is intended to be used as a central monitoring station on those patients being monitored by pulse oximeter and infusion pump medical devices. It is used to provide a secondary display of the data from the medical devices to the centrally located TS2000 System display. It is intended for use by healthcare professionals trained in the use of the equipment only.

The TS2000 is intended for use by healthcare professionals thoroughly familiar with the features and operations of the TS2000. The TS2000 is intended to supplement and not to replace any part of the current device monitoring procedures.

The TS2000 is not considered in and of itself to be diagnostic without skilled interpretation and does not replace physician's care

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



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

510(k) Number K973640

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____