K002604

510(k) Summary of Safety and Effectiveness

Submitter Information:

FEB 0 7 2002

Invivo Research Inc.
12601 Research Parkway
Orlando, FL 32826
407-275-3220
Contact: Mr. Francis Casey

Product Name:

Proprietary: Centurion™ 2000 Central Station with Arrhythmia Patient Monitoring System

Common Name	Classification No.	Class	Regulation Number
Cardiac Monitor	74DRT	II	21 CFR 870.2300
Pulse Rate Monitor	74BWS	II	21 CFR 870.2300
Pulse Oximeter	74DQA	II	21 CFR 870.2700
Radiofrequency physiological signal transmitter and receiver	74DRG	II	21 CFR 870.2910
Arrhythmia detector & alarm	74DSI	III	21 CFR 870.1025
Medical Cathode-ray Tube Display	74DXJ	II	21 CFR 870.2450
ST Segment Monitor with Alarm	74MLD	III	21 CFR 870.1025

Predicate Devices:

The primary predicate device(s) is: the Centurion™ 4000 Central Station with Arrhythmia Patient Monitoring System (510(k) number K980045). Other secondary predicate devices include: PCI/Vitalcom Inc. Central Station with Arrhythmia Monitor (510(k) numbers K962473 and K925411); the Datascope VISA Central Station with Arrhythmia Monitor (510(k) number K913676); the Critikon Central Station with Arrhythmia Monitor (510(k) number K933404); and the Datex CS/3 Arrhythmia Work Station Monitoring System (510(k) # K974747). These predicate devices have similar performance specifications as the Centurion™ 2000 Central Station with Arrhythmia Patient Monitoring System.

A major difference between the Centurion™ 2000 Central Station with Arrhythmia Patient Monitoring System and the Centurion™ 4000 Central Station with Arrhythmia Patient Monitoring System (510(k) number K980045) is the telemetry transmission frequencies. The newer Centurion 2000 utilizes the WMTS transmission frequencies. The predicate device for this particular feature is the Siemens MultiView Workstation Infinity System (510(k) number K003179), which has also added the capability of telemetry transmissions in the 608 to 614 MHz region to its pre-existing central station.

This Siemens MultiView transmitter also incorporates an SpO2 feature in the body of the transmitter, which is also a new feature of the Centurion™ 2000 Central Station System.

The SpO2 technology used in the the Centurion™ 2000 Central Station transmitters is the Nonin Medical X-Pod® SpO2 device which plugs directly into the T3300 transmitter. The SpO2 data and status are transmitted to the Central Station with the patient's ECG data. No modification has been made to the Nonin Medical X-Pod® device for its use with this system. The primary predicate device for this feature is the Nonin Medical PalmSAT®, Model 2500 Pulse Oximeter (510(k) number K002690). In addition. This same technology is used in the following devices: LaMont Medical Waratah and Cardinal Digital EEG/Sleep Acquisition System (510(k) K990522; Zymed EasiView Telemetry System (510(k) K001308). The SpO2 technology used in the the Centurion™ 2000 Central Station transmitters is also considered equivalent to these devices using this same Nonin Medical SpO2 technology.

Device Description:

The Centurion™ 2000 Central Station with Arrhythmia Monitoring System is a Central Station monitor comprised of a standard VGA display, standard commercial Personal Computer (PC) base systems, and hardware used to install the Network communications system (i.e. spread-spectrum transceivers and UHF telemetry receivers).

The Centurion™ 2000 Central Station with Arrhythmia Monitoring System can provide the centralized display, storage and recording (or printing) of patient vital sign and waveform data that is being monitored at the Invivo Research Inc. Millennia 3500 Series bedside monitors or spread-spectrum/UHF telemetry receivers.

Data accumulated at the Millennia 3500 Series bedside monitors is sent via a proprietary spread-spectrum LAN (local area network) to the Central Station for display, storage, and/or printing. ECG and SpO2 data accumulated from any of the Invivo Research Inc. telemetry transmitters is sent directly to the Central Station on standard WMTS UHF telemetry frequencies. The Central Station oversees all communications activities, allowing each system component to pass information along without interruption of patient monitoring.
The Central Station with Arrhythmia monitoring provides alarm detection and reporting for all patient parameters that are available to the Central Station, including arrhythmia monitoring for up to 40 patients. The Central Station alarm capability supplements the existing bedside monitor alarm capability (alarms at both locations).

The Central Station can provide storage of patient data for 40 patients for up to 72 hours. This includes waveform and patient parameter data for all available parameter values. The waveform and parameter data that has been stored in a patient file at the Central Station can be retrieved and reviewed on the display or printed out on a laser printer.

Intended Uses:

The Invivo Research Inc. The Centurion™ 2000 Central Station Arrhythmia Patient Monitoring is intended for general hospital or clinical use by medical professionals whenever it is required to monitor patients' cardiac arrhythmias during ECG monitoring. The need to monitor these arrhythmias is most commonly encountered in the intensive care areas of the hospital during patient monitoring. This device is available for sale only upon the order of a physician or other related licensed medical professional, and not intended for any home use applications..

Technological Comparison to Predicate Device(s):

The Invivo Research Inc. Centurion™ 2000 Central Station with Arrhythmia Monitoring System uses the same type of technology (i.e. personal computers and UHF analog or digital spread-spectrum transceivers) that are found in the predicate devices listed above.

Summary of Performance Testing:

The Invivo Research Inc. Centurion™ 2000 Central Station with Arrhythmia Monitoring System conforms with national and available international product safety standards for electrical, electromagnetic compatibility, and cardiac monitoring.

Tests demonstrating consideration and mitigation of the identified potential hazards for this device have been developed, and have been completed for this device. Conformance to the product development procedures and plans are assured by the application of the system tests, design reviews, and product verification and validation testing performed prior to product release.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 7 2002

Mr. Francis X. Casey
Vice-President, Regulatory Affairs
Invivo Research, Inc.
12601 Research Parkway
Orlando, FL 32826

Re: K002604
Trade Name: Centurion™ 2000 Central Station Arrhythmia Patient Monitoring System
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: DSI
Dated: November 7, 2001
Received: November 9, 2001

Dear Mr. Casey:

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.

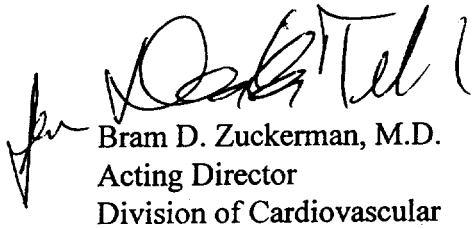
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K002604

Device Name: CENTURION 2000 CENTRAL STATION ARRNYTHMIA PATIENT MONITORING SYSTEM

Indications For Use:

The Invivo Research Inc. The Centurion™ 2000 Central Station Arrhythmia Patient Monitoring is intended for general hospital or clinical use by medical professionals whenever it is required to monitor patients' cardiac arrhythmias during ECG monitoring. The need to monitor these arrhythmias is most commonly encountered in the intensive care areas of the hospital during patient monitoring. This device is available for sale only upon the order of a physician or other related licensed medical professional.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002604

Prescription Use ✓ OR Over-The-Counter Use ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)