

NOV 16 1998

K980045

**510(k) Summary of Safety and Effectiveness**

**Submitter Information:**

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

**Product Name:**

Proprietary: Centurion™ Central Station with Arrhythmia Patient Monitoring System  
Common: Arrhythmia Detector and Alarm.  
Classification: Class III (see 21 CFR - 870.1025).

**Predicate Devices:**

The predicate device(s) are the 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), and the Critikon Central Station with Arrhythmia Monitor (510(k) number K933404). These predicate devices have the same performance specifications as the Centurion™ Central Station with Arrhythmia Patient Monitoring System

**Device Description:**

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

The Centurion™ 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. Millennium 3500 Series bedside monitors or spread-spectrum/UHF telemetry receivers.

Data accumulated at the Millennium 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. Data accumulated from any of the Invivo Research Inc. telemetry transceivers is sent directly to the Central Station on standard 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 8 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 8 patients for up to 24 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 thermal array recorder or laser printer.

#### **Intended Uses:**

The Invivo Research Inc. The Centurion™ 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™ Central Station with Arrhythmia Monitoring System uses the same type of technology (i.e. personal computers and UHF analog or digital spread-spectrum transponders) that are found in the predicate devices listed above, and are enumerated in Attachment 2 of this document.

#### **Summary of Performance Testing:**

The Invivo Research Inc. Centurion™ 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 will be complete before release of the 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.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Francis X. Casey  
Invivo Research, Inc.  
12601 Research Parkway  
Orlando, FL 32826

Re: K980045  
Centurion Central Station Arrhythmia Patient Monitoring System  
Regulatory Class: III (three)  
Product Code: 74 DSI  
Dated: August 31, 1998  
Received: September 1, 1998

Dear Mr. Casey:

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 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). 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.

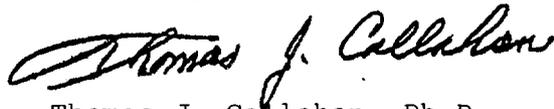
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 - Mr. Francis X. Casey

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/dsma/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): K980045

DEVICE NAME: CENTURION CENTRAL STATION WITH ARRHYTHMIA MONITORING

INDICATIONS FOR USE:

**Intended Uses:**

The Invivo Research Inc. The Centurion™ 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.

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

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Concurrent of CDRH, Office of Device Evaluation (ODE)

*Mark Krome*

Prescription Use  (Per 21 CFR 801.109)

OR Over-The-Counter-Use  (Optional Format 1-2-96)

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(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number \_\_\_\_\_