510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTER INFORMATION

AUG 0 2 2006

A.	Company Name:	Invivo Corporation
B.	Company Address:	12601 Research Parkway Orlando, FL 32826
C.	Company Phone: Company Fax:	(407) 275-3220 (407) 206-9658
D.	Contact Person:	Rusty Kelly Quality Control Manager Invivo Corporation
E.	Date Summary Prepared:	June 12, 2006

DEVICE IDENTIFICATION

A.	Generic Device Name:	Central Station
B.	Trade/Proprietary Name:	Vision VxC Central Station
C.	Classification:	Class II
D.	Product Code:	DSI "detector and alarm, arrhythmia"

DEVICE DESCRIPTION

The Vision VxC Central Station is designed specifically to provide centralized display for up to 16 patients, storage and recording (or printing) of patient vital sign and waveform data that are being monitored at the bedside by Invivo monitors and telemetry devices.

The Vision VxC Central Station can provide alarm detection and reporting for all vital sign parameters available to the central station for patient alarm surveillance. This alarm surveillance includes alarms reported by the bedside monitors and repeated to the central station as well as primary alarm surveillance for the patient worn WMTS telemetry transmitter device where there is no alarm notification capability on the transmitter worn by the patient.

Arrhythmia monitoring and ST segment detection capability is available as an option. The arrhythmia feature is equipped with password protection to prevent unauthorized users from turning off arrhythmia when a patient is being monitored. When a patient is monitored by arrhythmia the system will provide continuous monitoring of life-threatening alarms.

SUBSTANTIAL EQUIVALENCE

The Vision VxC Central Station is of comparable type and is substantially equivalent to the following predicate devices:

Predicate Device	Manufacturer	510(k) No.	Date Cleared
Escort-Link Central Station Monitor Model 20500	Medical Data Electronics	K982104	11/25/1998
Acuity Central Monitoring System	Welch Allyn Protocol, Incorporated	K022453	08/21/2002

INTENDED USE

The Vision VxC Series 4300 Central Station Monitor is intended to be used to provide, using a wireless LAN for communication, centralized surveillance and documentation of patient vital sign data and arrhythmia/ST monitoring for a variable number of Escort Bedside Monitors and a variable number of UHF telemetry transmitters in the hospital environment. It is intended for use by healthcare practitioners trained in the use of the equipment only.
The ST algorithm has been tested for accuracy of the ST segment measurement data. The significance of the ST segment changes must be determined by a physician

COMPARISON TO PREDICATE DEVICE:

The current version of the Vision Central Station was cleared to market under 510(k) K982104 under the name "Escort-Link Central Station Monitor Model 20500". The Vision Central Station has been modified as follows:

- The current arrhythmia detection and ST segment analysis algorithm library was replaced with the Mortara Instrument Incorporated product. This same library is used in the Welch Allyn Acuity Central Station, which was cleared to market via 510(k) K022453.
- The current Vision VxC platform was updated with new hardware and electronics to prevent product obsolescence.
- The current operating system was updated to Windows XP Embedded.
- The Link Auxiliary Base has previously been replaced with a Telemetry Receiver Platform which incorporates a WMTS receiver in a more compact enclosure (reference 510(k) K012336).

The modified Vision Central Station will be marketed as the Vision VxC Central Station.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Vision Vx C Central Station and the predicate devices has been performed. The results of this comparison demonstrate that the Vision VxC Central Station is equivalent to the marketed predicate devices in technological characteristics.

ENVIRONMENTAL AND NON-CLINICAL TESTING:

Applicable environmental and non-clinical testing was performed per EN IEC 60950, AANSI/AAMI EC 57; 1998, EN 55022 and EN 55024. The Vision VxC Central Station passed all tests.

PERFORMANCE DATA

The performance data included in this submission to compare equivalency of the Vision VxC Central Station with the Escort Link Central Station and the Acuity Central Monitoring System confirms that the performance requirements for accuracy and precision were met and indicates substantial equivalence to the predicate devices. Equivalent performance in meeting user requirements was also determined.

Summary of Performance Testing:

This device was validated using patient simulators under simulated use conditions. The functional requirements and user needs were verified to have been met.

CENTRAL STATION

PARAMETER:	REQUIREMENT	RESULTS
Display Type:	Flatpanel 19" LCD	Pass
Central Processor:	Intel Pentium	Pass
User Interface:	Touchscreen and/or mouse	Pass
Operating System:	Microsoft Windows XP Embedded	Pass
Number of Patients Monitored:	1 to 16 (up to 16 designated for telemetry)	Pass
Parameters Monitored:	ECG, Resp, IBP (SYS, DIA, MEAN), NIBP (SYS, DIAS, MEAN), SpO2, ETCO2, Temp	Pass
Max Parameters Monitored :	20	Pass
Trending:	Tabular for 16 patients, all parameters; up to 72 hours at 1, 2, 3, 4, 5, 15, 30, 60, 120, and 180 min. intervals	Pass
Alarm History Storage:	1000 events within 72 hours per patient; 20 sec per event	Pass
Documentation:	Thermal array recorder and/or laser printer	Pass
AC Main:	90-130/180-260 VAC, 47-63 Hz selectable, 6 amps@115V	Pass
Power Supply:	235 W	Pass
Operating Temperature:	10 to 40° C	Pass
Storage Temperature:	-40 to 75° C	Pass
Relative Humidity:	5 to 95 %	Pass
Standards	UL 60950	Pass

TELEMETRY RECEIVER PLATFORM

PARAMETER:	REQUIREMENT	RESULTS
Alarm History Storage:	1000 events within 72 hours per patient; 20 sec per event	Pass
Documentation:	Thermal array recorder and/or laser printer	Pass
AC Main:	115/230 VAC, 60/50 Hz selectable, 4 amps@115V	Pass
Power Supply:	235 W	Pass
Input Voltage:	100-120 VAC / 200 - 240 VAC, selectable, 50/60 Hz	Pass
Input Current:	6 Amp max @ 115V (20A Max inrush cold start), 3 Amp max @ 230 V (10A Max inrush cold start)	Pass
Telemetry Band:	FCC WMTS (608-614 MHz)	Pass
Operating Temperature:	10 to 40° C	Pass
Relative Humidity:	10 to 90 %	Pass
Standards	UL 60950, FCC Part 15 (Spread Spectrum)	Pass

ARRHYTHMIA ANALYSIS OPTION

PARAMETER:	REQUIREMENT	RESULTS
Number of Arrhythmia Channels:	1 to 16 (dual vector)	Pass
Types of Detected Events:	Asystole, VFIB, VTACH, Couplet, High and Low Heart Rate, High Abnormal Count, Bigeminy, Trigeminy, V.RUN, V.Rhythm, Multi-Focal, R-ON-T, Pause	Pass
Type of Algorithm:	Heuristic algorithm using template matching and feature extraction	Pass
QRS Detection Sensitivity	AHA ≈99.88%, MIT ≈99.93%	Pass
QRS Detection Positive Predictivity	AHA ≈99.89%, MIT ≈99.85%	Pass
PVC Detection Sensitivity	AHA ≈94.07%, MIT ≈95.44%	Pass
PVC Detection Positive Predictivity	AHA ≈97.72%, MIT ≈96.60%	Pass
PVC Detection False Positive Rate	AHA ≈0.22%, MIT ≈0.23%	Pass
Alarm Displays	arrhythmia alarm must display	Pass
Alarm Tones	arrhythmia alarm must sound	Pass
Alarm Recordings	arrhythmia alarm must generate an alarm recording if configured	Pass
Alarm Event History	arrhythmia alarm must generate event history record	Pass
Maximum Patient Load	16 patient	Pass
Standard	AAMI/ANSI EC 57: 1998	Compliant

ST ANALYSIS OPTION

PARAMETER:	REQUIREMENT	RESULTS
Number of ST Channels:	1 to 16, but no more than arrhythmia channels	Pass
Alarms:	high and low for both vectors; can be recorded and/or stored as events	Pass
Standard	AAMI/ANSI EC 57: 1998	Compliant

Conclusion:

The verification and validation activities for the modified Vision Central Station confirm that all identified risks have been mitigated and that this device operates as designed and intended. The test results demonstrate the modified Vision Central Station is substantially equivalent to the predicate device cleared to market via 510(k) K982104 and the other predicate devices identified in this submittal.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 2 2006

Invivo Corporation
c/o Ms. Maria Keelan
Regulatory Affairs Specialist
12601 Research Parkway
Orlando, FL 32826

Re: K061675
Vision VxC Central Station
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm
Regulatory Class: Class II (two)
Product Code: MHX
Dated: July 7, 2006
Received: July 10, 2006

Dear Ms. Keelan:

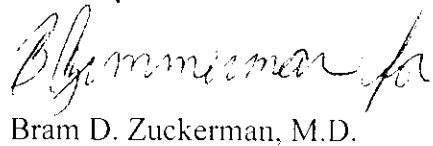
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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,



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

Enclosure

K061675

Indications for Use

510 (k) Number (if known):_____

Device Name: **Model 4300 Vision VxC Central Station**

Indications for Use:

The Vision V x C series 4300 central station monitoring system is intended to be used to provide, using a wireless LAN for communication, centralized surveillance and documentation of patient vital sign data and arrhythmia/ST monitoring for a variable number of Escort Bedside Monitors and a variable number of UHF telemetry transmitters in the hospital environment. It is intended for use by healthcare practitioners trained in the use of the equipment only.

The ST algorithm has been tested for accuracy of the ST segment measurement data. The significance of the ST segment changes must be determined by a physician.

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K061675

Prescription Use ____√____ AND/OR Over-The Counter Use
(Part CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)