K091971

AUG 2 7 2009

510(k) Summary of Safety & Effectiveness **Date: June 29, 2009**

Submitter Name & Address:	Corventis, Inc. 2033 Gateway Place Suite 100 San Jose, CA 95110
Contact Person:	Madhuri Bhat, VP, Clinical & Regulatory Affairs 408-790-9306 (phone) 408-790-9350 (fax)
Trade/Proprietary Name:	AVIVO™ Mobile Patient Management System NUVANT™ Mobile Cardiac Telemetry System
Common/Usual Name:	Mobile Patient Management System Mobile Cardiac Telemetry System
Classification Name:	Arrhythmia Detector and Alarm (21 CFR 870.1025, Product Code DSI) Patient Physiological Monitor (with arrhythmia detection) (21 CFR 870.1025, Product Code MHX)
Class:	Class II, Special Controls
510(k):	Special 510(k): Device Modification

Predicate Devices:

1. AVIVO Mobile Patient Management System, Corventis, Inc., cleared by FDA under 510(k) number K083287; 21 CFR 870.1025, DSI "Arrhythmia Detector and Alarm", and 21 CFR 870.1025, MHX "Patient Physiological Monitor (with arrhythmia detection)"

2. NUVANT Mobile Cardiac Telemetry System, Corventis, Inc. cleared by FDA under 510(k) number K090606; 21 CFR 870.1025, DSI "Arrhythmia Detector and Alarm", and 21 CFR 870.1025, MHX "Patient Physiological Monitor (with arrhythmia detection)"

3. Heartrak Smart AF, Universal Medical Incorporated, cleared by FDA under K071130; 21 CFR 870.0290, DXH "Telephone Electrocardiograph Transmitter and Receiver"

4. CardioNet ECG Monitor with Arrhythmia Detection Model CN1005, CardioNet Inc., cleared by FDA under K072558; 21 CFR 870.1025, DSI "Arrhythmia Detector and Alarm"

1. BACKGROUND INFORMATION

The following two models are the subject devices of this Special 510(k):

- The AVIVO™ Mobile Patient Management System (hereafter referred to as "subject AVIVO")
- The NUVANT™ Mobile Cardiac Telemetry System (hereafter referred to as "subject NUVANT")

The subject AVIVO is a modification of the AVIVO Mobile Patient Management System cleared by the FDA under K083287 (hereafter referred to as "predicate AVIVO); whereas the NUVANT is a modification of the NUVANT Mobile Cardiac Telemetry System cleared by the FDA under K090696 (hereafter referred to as "predicate NUVANT"). The predicate AVIVO and the predicate NUVANT are intended for the monitoring of ECG and other vital parameters, in which ECG is collected when the heart rate based algorithm embedded in the device detects an abnormal heart rate, i.e. a heart rate that goes beyond a non-user adjustable predetermined threshold.

The modification made to the subject AVIVO and NUVANT permits the devices to collect ECGs based on morphology / timing of the wave form in addition to the rate. This modification enables the subject devices to discriminate waveforms based on morphology and also count ectopic beats (such as PVCs and PACs) and calculate atrial fibrillation burden of the patient.

The intent of the subject devices remains the same as that of the predicate devices, which is to monitor ECG and other vital parameters. No change has been made to the Indication for Use Statements.

2. INDICATION FOR USE STATEMENT

a. AVIVO

The AVIVO™ Mobile Patient Management System is intended to continuously record, store, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. The AVIVO Mobile Patient Management System also monitors, derives and displays:

- ECG
- Heart Rate (including HR variability)
- Activity
- Posture
- Body Temperature
- Respiration rate (including RR variability)

- Body fluid status

b. NUVANT

The NUVANT™ Mobile Cardiac Telemetry (MCT) System is intended to continuously measure, record, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. The NUVANT system model monitors, derives and displays:

- ECG
- Heart rate

The Systems may also monitor, derive and display:

- Activity
- Posture
- Body temperature
- Respiration rate (including RR Variability)
- Body fluid status
- Heart rate variability

3. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The NUVANT is essentially the AVIVO with the addition of a patient trigger magnet. The following are the system components of both models:

- PiiX™ (aka Adherent Device)
- Patient Trigger Magnet (specific to NUVANT)
- zLink™ (aka Gateway)
- Server

a. PiiX

The PiiX is a patient-worn device which is applied to the patient's torso. It contains the ECG electrodes for recording ECG and heart rate data; the impedance sensor for collecting respiration and body fluid data; the accelerometer for collecting activity and posture. Additionally, resided in the PiiX is a heart rate, timing and morphology based arrthythmia detection algorithm which allows the system to discriminate waveforms based on morphology and also count ectopic beats (such as PVCs and PACs) and calculate atrial fibrillation burden of the patient.

Sensor data and ECG collected by the PiiX are transmitted to the Server via zLink.

b. Patient Trigger Magnet

Specfic to the NUVANT is the Magnet, which is part of the Patient Trigger feature. This external piece accompanying the PiiX and is used by the patient to manually trigger the ECG collection when he/she experiences symptoms. Patient triggers the ECG collection by swiping the Magnet across the PiiX. The ECG waveform will then be transmitted to the Server via zLink.

c. zLink

zLink receives information from the PiiX and transmits them to the Corventis Server. It also interacts with the Corventis Server to receive configuration updates and other relevant hardware diagnostic information.

d. Server

The Server receives sensor data from the PiiX via zLink. Data from the accelerometer is derived into activity and posture; data from the impedance sensor is derived into respiration rate, respiration variability and body fluid status. ECG and heart rate are presented without derivation.

Additionally, the secure server performs the following functions:

- Display the physiological parameters in trend graphs format.
- Display ECG waveform that corresponds to a detected arrhythmia
- Provide patient's Afib burden, if applicable
- Provide visual notifications for the detected arrhythmia.
- Provide the users the ability to acknowledge or dismiss events.

e. Transmission Technologies

The communication between the PiiX and the zLink is enabled via the BlueTooth™ Technology. The zLink transmits the data to the Server via cellular technology, where healthcare professionals can access with standard browsers.

4. PREDICATE DEVICES

Four (4) predicate devices have been identified:

1. AVIVO Mobile Patient Management System, Corventis, Inc., cleared by FDA under 510(k) number K083287; 21 CFR 870.1025, DSI "Arrhythmia Detector and Alarm", and 21 CFR 870.1025, MHX "Patient Physiological Monitor (with arrhythmia detection)"

2. NUVANT Mobile Cardiac Telemetry System, Corventis, Inc. cleared by FDA under 510(k) number K090606; 21 CFR 870.1025, DSI "Arrhythmia Detector and Alarm", and 21 CFR 870.1025, MHX "Patient Physiological Monitor (with arrhythmia detection)"

3. Heartrak Smart AF, Universal Medical Incorporated, cleared by FDA under K071130; 21 CFR 870.0290, DXH "Telephone Electrocardiograph Transmitter and Receiver"

4. CardioNet ECG Monitor with Arrhythmia Detection Model CN1005, CardioNet Inc., cleared by FDA under K072558; 21 CFR 870.1025, DSI "Arrhythmia Detector and Alarm"

Table 2 below summarizes the compared features and the corresponding predicate devices.

Table 2 Features comparison and corresponding predicate devices

Features being compared	Subject Devices	Predicate Devices
Arrhythmia Detection Algorithm	Modified AVIVO Modified MCT	Heartrak Smart AF (K07113) & Cardionet CN1005 (K072558)
All other features	Modified AVIVO Modified MCT	Original AVIVO (K083287) Original MCT (090696)

5. CONCLUSION

The modified arrhythmia detection algorithm made to the AVIVO Mobile Patient Management System and NUVANT™ Mobile Cardiac Telemetry (NUVANT) System does not change the intended use or the fundamental scientific technology of the devices. As supported by the descriptive information and the design verification tests, it is concluded that the AVIVO Mobile Patient Management System and NUVANT™ Mobile Cardiac Telemetry (NUVANT) Systems are as safe and as effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

AUG 2 7 2009

Corventis, Inc.
c/o Madhuri Bhat
VP, Clinical and Regulatory Affairs
2033 Gateway Place, Suite 100
San Jose, CA 95110

Re: K091971
Trade/Device Name: AVIVO™ Mobile Patient Management System; and, NUVANT™ Mobile Cardiac Telemetry System
Regulatory Number: 21 CFR 870.1025
Regulation Name: Arrhythmia detector and alarm (including ST-segment measurement and alarm)
Regulatory Class: Class II (Two)
Product Code: DSI
Additional Product Code: MHX
Dated: August 18, 2009
Received: August 20, 2009

Dear Mr. Bhat:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Richmond

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

Enclosure

Indications for Use

510(k) Number (if known): ~~N/A~~ K091971

Device Names: AVIVO™ Mobile Patient Management System

Indications for Use:

The AVIVO™ Mobile Patient Management System is intended to continuously record, store, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. The AVIVO Mobile Patient Management System also monitors, derives and displays:

- ECG
- Heart Rate (including HR variability)
- Activity
- Posture
- Body Temperature
- Respiration rate (including RR variability)
- Body fluid status

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Witcher

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091971

Indications for Use

510(k) Number (if known): ~~N/A~~ K091971

Device Names: NUVANT™ Mobile Cardiac Telemetry System

Indications for Use:

The NUVANT™ Mobile Cardiac Telemetry (NUVANT) System is intended to continuously measure, record, and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias. The NUVANT system model monitors, derives and displays:

- ECG
- Heart rate

The Systems may also monitor, derive and display:

- Activity
- Posture
- Respiration rate (including RR Variability)
- Body fluid status
- Heart rate variability

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Vachner

(Division Sign-Off)

Division of Cardiovascular Devices

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