

## 510(k) Summary

As required by 21 CFR, part 807.92

Submitted By: Inovise Medical, Inc.  
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Contact: Earl Anderson  
Director, Quality and Regulatory

Date Prepared: May 14, 2013

Proprietary Name: AUDICOR® CPAM with SDB (Single Sensor)

Common/ Usual Name: Ambulatory Monitor / Acoustic Cardiograph

Classification: 870.2800, MLO, class II, Electrocardiograph, Ambulatory (with analysis program)  
868.2375, MNR, Ventilatory Effort Recorder

Performance Standards: AAMI EC38 and AAMI EC57

Intended Use: The AUDICOR System when used with an AUDICOR Sensor on the chest wall and properly attached Holter unit, is intended for use on adults 18 years of age and older in acquiring, analyzing and reporting ECG, heart sound, body position, Sleep Disordered Breathing (SDB) and snoring detection and to provide interpretation of the data in an integrated report for consideration by physicians. The SDB analysis and reporting is intended for use on adult patients only as a screening device for obstructive or mixed apnea to determine the need for evaluation by polysomnography based on the patient's score. Patients screened for SDB should have periods of sleep of at least 4 hours duration during which the ECG is predominantly sinus rhythm in nature. The AUDICOR recording may be obtained at any location specified by a physician including home, hospital or clinic. The device is intended for use only under the direct supervision of a physician.

Device Description: The AUDICOR System employs the Hemo ambulatory recording device to capture 10-second snapshots or up to 48 continuous hours of physiologic data. ECG, heart sounds, body position, sleep disordered breathing, snoring sounds, and activity level are interpreted from the physiologic signals captured. The AUDICOR System includes software to analyze recorded data, then display and present a summary of patient data over time in a trended format. Notable events are detected and displayed for review by the clinician.

The AUDICOR System analyzes and reports the following parameters:

- Heart rate including bradycardia and tachycardia events
- Atrial fibrillation
- ECG beat classification and morphology grouping with user-editing
- Heart rate variability
- Snoring detection
- Sleep disordered breathing (apnea/hypopnea) events
- Sleep disordered breathing score
- Activity level

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- Body position
- Heart sound and combined ECG/heart sound measurements
- Heart rate distributions of heart sound parameters

The clinician can review automatically detected events and measurements, and modify them as well as modify the interpretative statements generated.

Non-Clinical  
Performance  
Testing

In support of design verification, the AUDICOR System has been tested to the applicable requirements of the following standards, and shown to comply.

- EN 60601-1 Standard for Medical Electrical Equipment: General Requirements for Safety
- EN 60601-1-2 Standard for Medical Electrical Equipment Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
- ANSI/AAMI EC38: Ambulatory Electrocardiographs
- ANSI/AAMI EC57: Test and Reporting Performance Results of Cardiac Rhythm and ST-segment Measurement Algorithms

The modifications to the AUDICOR System are constrained to software elements. These modifications have no impact on the mechanical, electromagnetic compatibility, biocompatibility or electrical safety characteristics of the previously-cleared AUDICOR CPAM system. The AUDICOR System did undergo all applicable and required Verification and Validation activities and successfully passed all test protocols.

Clinical  
Performance  
Testing

Retrospective clinical tests were performed to evaluate the performance of the new body position capability and the modified heart sound capability.

**Body Position:** A study was designed and undertaken on a group of subjects representative of those intended to use the device and that established AUDICOR body position accuracy in comparison to idealized gold-standard performance. There were no complications or adverse events during the course of the study. The results of this study conclusively shows AUDICOR performance to be equivalent to the limits achievable using the same technology employed by the predicate device. Evaluation of performance metrics effectively demonstrates performance that is substantially equivalent to the predicate device.

**Single Sensor Heart Sound:** A study was designed and undertaken that compares AUDICOR heart sound algorithm performance using a single AUDICOR sensor to that of the predicate two-sensor AUDICOR system. The retrospective study re-employed datasets initially used for obtaining FDA clearance for the two-sensor system on a group of patients representative of those the device is intended for. The results of the study show that AUDICOR heart sound algorithms modified for use with a single sensor have statistically equivalent performance as that of the two-sensor system. This statistical equivalency in performance is the basis for the claim of substantial equivalency with the predicate device.

**Technological Characteristics:** The AUDICOR System and the predicate devices are technologically equivalent in that the devices:

- 1) Are small, wearable, battery-powered devices
- 2) Acquire ECG data from patients using limited ECG leads
- 3) Analyze the ECG signal to detect periods of sleep-disordered breathing
- 4) Acquire a sound signal for detection of snoring
- 5) Analyze the signals from an accelerometer to derive body position and activity level
- 6) Use non-volatile memory to store patient data for download to the analysis module of the system

The AUDICOR System is different from the predicates in the following ways:

- 1) The previously-cleared AUDICOR System employed the use of two dual-purpose AUDICOR sensors attached to the chest wall. The modified AUDICOR system is now specified for use with a single dual-purpose AUDICOR sensor.

**Substantial Equivalence:** The predicate devices for the added algorithm for reporting of body position and the modification to existing AUDICOR algorithms to accommodate single-sensor use are:

1. AUDICOR CPAM (510(k) (K120462), and
2. VivoMetrics LifeShirt with VivoLogic Analysis Software (510(k) K011903)

The intended uses of the predicates are similar in that they are ambulatory monitors that record and analyze ECG, heart sounds, body position and sleep-disordered breathing from ECG. The VivoMetrics device can also collect signals from external devices such as blood pressure monitors but this does not represent a critical difference to the intended use of the device when used as labeled.

The predicate for the new body position detection feature is the Vivometrics LifeShirt System with VivoLogic Analysis Software (K011903). The Vivometrics LifeShirt System contains a tri-axial accelerometer and the VivoLogic Software running on a computer processes the tri-axial accelerometer to determine body position that is then made available to the user. The AUDICOR System also incorporates a tri-axial accelerometer and an automated signal processing algorithm that runs on an AUDICOR enabled computer that processes the accelerometer signals to determine body position. In this way both devices incorporate the same basic tri-axial accelerometer technology and report the same information to the user concerning body position.

**Conclusion:** The combination of non-clinical tests outlined and summarized above and described in the Declaration of Conformity together with clinical performance testing, also outlined above, demonstrates the subject device is substantially equivalent to the predicate devices noted with respect to principles of operation, intended use and technological characteristics.



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

October 11, 2013

Inovise Medical, Incorporated  
Mr. Earl Anderson  
Director, Quality and Regulatory  
8770 SW Nimbus Avenue, Suite D  
BEAVERTON OR 97008-7196

Re: K130660  
Trade/Device Name: AUDICOR CPAM with SDB (Single Sensor)  
Regulation Number: 21 CFR 870.2800  
Regulation Name: Medical Magnetic Tape Recorder  
Regulatory Class: II  
Product Code: MLO, MNR  
Dated: September 9, 2013  
Received: September 10, 2013

Dear Mr. Anderson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Tejashri Purohit Sheth, M.D.  
Clinical Deputy Director

FOR

Kwame Ulmer M.S.  
Acting Division Director  
Division of Anesthesiology, General Hospital,  
Respiratory, Infection Control and  
Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

K130660:

Device Name: AUDICOR® CPAM with SDB (Single Sensor)

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Prescription Use XXX  
(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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Anya C. Harry  
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Digitally signed by Anya C. Harry -S  
DN: c=US, o=U.S. Government, ou=HHS,  
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