K120462

510K Summary of Safety and Effectiveness

SEP 20 2012

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: February, 08 2012

Proprietary Name: Modification to AUDICOR CPAM (Cardiopulmonary Ambulatory Monitor)

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 AUDICOR Sensors 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, sleep disordered breathing, snoring detection and activity level data and to provide interpretation of the data in an integrated report for consideration by physicians. The sleep disordered breathing analysis and reporting is intended for use on adult patients only as a screening device to determine the need for evaluation by polysomnography based on the patient's score.

Subjects screened for sleep disordered breathing 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 CPAM with SDB (Cardiopulmonary Holter with Sleep Disordered Breathing detection) is an ambulatory device that can be used to capture 10-second snapshots or up to 48 hours of continuous data from ECG, heart sounds, sleep disordered breathing and snoring detection, and activity level, particularly in patients suspected of heart failure or acute coronary syndrome. The Audicor CPAM with SDB includes software to display, analyze and provide 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
- 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.

Test Summary & Conclusion: 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

Substantial Equivalence: The added algorithms for reporting of sleep disordered breathing, snoring and activity are substantially equivalent to:

1. Audicor CPAM (510(k) K110569), and
2. Spacelabs Healthcare Pathfinder SL Holter Analyzer (510(k) K110001)
3. Nox Medical Nox T3 Sleep Recorder (510(k) K082113)

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

- Are small, wearable, battery-powered devices
- Acquire ECG data from patients using limited ECG leads
- Analyze the ECG signal to detect periods of sleep disordered breathing
- Acquire a sound signal for detection of snoring
- Analyze the signals from an accelerometer to derive activity level
- 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:

- Does not acquire EEG, EMG or EOG signals, or nasal pressure

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

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SEP 20 2012

Re: K120462
Trade/Device Name: Audicor® CPAM with SDB (Cardiopulmonary Ambulatory Monitor with Sleep Disordered Breathing)
Regulation Number: 21 CFR 870.2800
21 CFR 868.2375
Regulation Name: Medical Magnetic Tape Recorder, Breathing Frequency Monitor
Regulatory Class: II
Product Code: MLO, MNR
Dated: September 6, 2012
Received: September 10, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Audicor System (CPAM with SDB)

Indications For Use:

The AUDICOR System when used with AUDICOR Sensors 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, sleep disordered breathing and snoring detection and to provide interpretation of the data in an integrated report for consideration by physicians. The sleep disordered breathing 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.

Subjects screened for sleep disordered breathing 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.

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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(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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