APR 1 1 2014

510k 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: June 14, 2013 (Revised April 11, 2014 – Test Summary and Conclusions)

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

Common/ Usual Name: Ambulatory Monitor / Acoustic Cardiograph

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

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 (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 AUDICOR AM (Hemo) ambulatory recording device to capture 10-second snapshots or up to 48 continuous hours of physiologic data. ECG, heart sound, 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

- 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: 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

Prospective clinical testing was performed to evaluate the performance of the technology modification for SDB detection. A study was designed and undertaken that compares AUDICOR SDB detection performance of the predicate device (K120462) to that of the subject device. The prospective study was undertaken at Taipei Veterans General Hospital in Taipei, Taiwan. The study resulted in development of a testset of 77 recordings which were used for the performance comparison. Physician-overread results from concurrent polysomnography recordings on the test subjects was the clinical gold-standard used for establishing PSG-AHI positive and PSG-AHI negative cohorts. The ECG-based SDB algorithm of the predicate device was applied to the concurrent ECG data recorded from the subjects. The accelerometer-based SDB algorithm of the subject device was applied to concurrent accelerometer data recorded from the subjects. Using these algorithm results, statistical analyses were undertaken to compare the SDB accuracy of the predicate device to that of the subject device. Substantial equivalence of the subject device's algorithm performance to that of the predicate device was demonstrated through this statistical comparison. (see Attachment 6, "Clinical Study Report", "K131883 – Response to reviewer's request for additional information, dated 09/12/2013"). This statistical equivalency in performance is central to the claim of substantial equivalency with the predicate device.

Substantial Equivalence: The reporting of SDB detection of the subject device is substantially equivalent to AUDICOR CPAM with SDB detection (K120462). Any differences between the subject device and the predicate do not raise new questoins of safety and effectiveness.

Technological Characteristics: The subject device and the predicate device 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) Acquire a sound signal for detection of snoring
4) Analyze the signals from an accelerometer to derive activity level
5) Use non-volatile memory to store patient data for download to the analysis module of the system

The subject device is different from the predicates in the following ways:

1) The predicate device uses ECG waveform signals for SDB detection. Through a technology change, the subject device accomplishes SDB detection using waveform signals obtained from an extant tri-axial accelerometer housed within the Hemo ambulatory recording device. This accelerometer was previously described within K120462 where it as used for activity level assessment only.

Conclusion: The combination of non-clinical tests outlined above and described in the Declaration of Conformity together with clinical performance testing, also outlined above, demonstrates the subject device is as safe and as effective and performs substantially equivalent to the predicate device noted.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 11, 2014

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

Re: K131883
Trade/Device Name: AUDICOR® CPAM with SDB
Regulation Number: 21 CFR 868.2375
Regulation Name: Ventilatory Effort Recorder
Regulatory Class: II
Product Code: MNR, MLO
Dated: March 5, 2014
Received: March 6, 2014

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" (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

Erin I. Keith, M.S.
Acting 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

Device Name: **AUDICOR® CPAM with SDB**

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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 (SDB) and snoring detection and to provide interpretation of the data in an integrated report for consideration by physicians.

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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)

Anya C. Harry -S
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