DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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March 18, 2016

Inovise Medical, Inc.
Earl Anderson
Director, Quality and Regulatory
8770 SW Nimbus Avenue, Suite D
Beaverton, Oregon 97008

Re: K151433
Trade/Device Name: AUDICOR CA300/CC100 Analyzer with SDB
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: MNR, MLO
Dated: February 9, 2016
Received: February 16, 2016

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 Industry and Consumer Education 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 Industry and Consumer Education 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.*

**Tejashri Purohit-Sheth, M.D.**
**Clinical Deputy Director**
**DAGRID/ODE/CDRH FOR**

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K151433

Device Name
AUDICOR CA300 / CC100 Analyzer with SDB

Indications for Use *(Describe)*

AUDICOR CA300/CC100 Analyzer with SDB is a software-only system intended to be used to analyze recordings from AUDICOR-compatible recording devices.

AUDICOR CA300/CC100 Analyzer with SDB is capable of analyzing, editing, storing and reporting ECG, heart sound, sleep-disordered breathing (SDB), snoring detection, body position and activity level. An interpretation of the analysis results is produced in an integrated report for consideration by physicians.

The AUDICOR CA300/CC100 Analyzer with SDB software is intended for use on adults 18 years of age and older. The SDB analysis and reporting is intended for use on adult patients 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.

AUDICOR CA300/CC100 Analyzer with SDB is intended to be used by trained operators under the direct supervision of a physician in a hospital or clinic environment.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

As required by 21 CFR, part 807.92

**Submitted By:** Inovise Medical, Inc.
8770 SW Nimbus Ave, Suite D
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Phone 503-431-3821
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**Contact:** Earl Anderson
Director, Quality and Regulatory

**Date Prepared:** February 9, 2016

**Date Revised:** March 18, 2016

**Proprietary Name:** AUDICOR CA300 / CC100 Analyzer with SDB

**Common/ Usual Name:** ECG, Heart Sounds and SDB Analyzer

**Classification:** Primary: 868.2375, MNR (Regulation Description: Breathing frequency monitor)
(Device Classification Name: Ventilatory effort recorder)
Subsequent: 870.2800, MLO, (Regulation Description: Medical magnetic tape recorder)
(Device Classification Name: Electrocardiograph, ambulatory, with analysis algorithm)

## Device Description:

AUDICOR CA300/CC100 Analyzer is a software-only system for the analysis of physiologic signals acquired through AUDICOR-compatible recording devices. Analysis results from ECG, heart sound, sleep-disordered breathing, snoring sounds, body position and activity levels are automatically interpreted. The AUDICOR CA300/CC100 software system allows for the review, edit, and storage of the analysis results. Reporting of analysis results is provided, together with patient data and notable events for review by the clinician.

The AUDICOR Analyzer software 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 events
- Sleep disordered breathing score
- Activity level
- Body Position
- Heart sound and combined ECG/heart sound measurements
- Heart rate distributions of heart sound parameters

## Intended Use:

AUDICOR CA300/CC100 Analyzer is a software-only system intended to be used to analyze recordings from AUDICOR-compatible recording devices.

AUDICOR CA300/CC100 is capable of analyzing, editing, storing and reporting ECG, heart sound, sleep-disordered breathing (SDB), snoring detection, body position and activity level. An interpretation of the analysis results is produced in an integrated report for consideration by physicians.

The AUDICOR CA300/CC100 Analyzer software is intended for use on adults 18 years of age and older.

The SDB analysis and reporting is intended for use on adult patients 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.

AUDICOR CA300/CC100 is intended to be used by trained operators under the direct supervision of a physician in a hospital or clinic environment.

## Technological Characteristics:

| Characteristic | Subject Device | Predicate (K131883) |
|---|---|---|
| **Intended Use** | AUDICOR CA300/CC100 Analyzer is a software-only system intended to be used to analyze recordings from AUDICOR-compatible recording devices. AUDICOR CA300/CC100 is capable of analyzing, editing, storing and reporting ECG, heart sound, sleep-disordered breathing (SDB), snoring detection, body position and activity level. An interpretation of the analysis results is produced in an integrated report for consideration by physicians. The AUDICOR CA300/CC100 Analyzer software is intended for use on adults 18 years of age and older. The SDB analysis and reporting is intended for use on adult patients 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. AUDICOR CA300/CC100 is intended to be used by trained operators under the direct supervision of a physician in a hospital or clinic environment. | 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 Classification** | MNR, Ventilatory Effort Recorder, MLO, class II, Electrocardiograph, Ambulatory (with analysis program) | MNR, Ventilatory Effort Recorder, MLO, class II, Electrocardiograph, Ambulatory (with analysis program) |
| ***General Functionalities:*** | | |
| **Data utilized from AUDICOR-compatible recording devices** | Yes | Yes |
| **Data display on PC for interpretation** | Yes | Yes |
| **Data analysis (computer, computer-assisted or manual)** | Computer-assisted | Computer-assisted |

| | | |
|---|---|---|
| **Comprehensive report generation** | Optional | Optional |
| ***ECG Analysis*** | | |
| **Channels** | 3 | 3 |
| **Minimum analysis interval** | 10 second snapshot | 10 second snapshot |
| **Typical analysis interval** | 24 – 48 hours | 24 – 48 hours |
| **Heart rate** | Yes | Yes |
| **Heart rate variability** | Yes | Yes |
| **ECG arrhythmia detection and classification** | Yes | Yes |
| **ECG morphology grouping and editing** | Yes | Yes |
| **Atrial Fibrillation** | Yes | Yes |
| ***Heartsound Analysis*** | | |
| **Heart sound analysis of single 10 second recordings** | Yes | Yes |
| **Minimum analysis interval** | 10 second snapshot | 10 second snapshot |
| **Typical analysis interval** | At least 4 hours, aggregated contiguous or periodic 10 second interval results | At least 4 hours, aggregated contiguous 10 second interval results |
| **Heart sound analysis aggregation of continuous 10s intervals, totaling up to 48 hours** | Yes | Yes |
| **Heart sound analysis aggregation of periodic sampling of 10s intervals, totaling up to 48 hours** | Yes | No |
| **Comprehensive set of heart sound parameters** | Yes | Yes |
| ***SDB Analysis*** | | |
| **Minimum analysis interval** | 4 hours | 4 hours |
| **SDBSS (Score)** | Yes | Yes |
| **Snoring detection** | Yes | Yes |
| ***Other Analyses*** | | |
| **Activity level** | Yes | Yes |
| **Body position** | Yes | Yes |
| ***Report Components*** | | |
| **Graphs, trends, statements** | Yes, with hourly and daily trends of ECG and heart sound parameters | Yes |
| **10 second reports** | Yes, with heart sound scalogram | Yes |
| **Cardiac report** | Yes, with cardiac cyclogram and reference ranges for heart sound parameters | Yes |
| **Sleep report** | Yes, with SDB events and snoring index also presented with respect to body position | Yes, with SDB events and snoring index |
| ***Miscellaneous*** | | |
| **Report patient triggered events** | Yes | Yes |
| **Signal quality verification** | Yes | Yes |

## Non-clinical Testing

The following quality assurance measures were conducted for the AUDICOR CA300/CC100 Analyzer software:

- Risk Analysis
- Design requirements and traceability
- Unit and system level software verification
- System level validation

In addition, the AUDICOR System has been tested for compliance with *ANSI/AAMI EC57: Test and Reporting Performance Results of Cardiac Rhythm and ST-segment Measurement Algorithms*.

The results of the verification and validation tests concluded that the functionality and performance of the AUDICOR CA300/CC100 Analyzer software are comparable to the currently marketed predicate device.

## Clinical Testing

The objective of the testing was to support the substantial equivalence claim for the new capability of aggregating periodically sampled heart sound measurements.

The testing approach involved retrospective analysis of AUDICOR AM data obtained from a total study population of 252 subjects. The study subjects included a cohort clinically diagnosed with heart failure and a cohort of subjects determined to be negative for heart failure.

Statistical analyses were performed that demonstrated both subject and predicate aggregation methods are statistically equivalent. These results support the substantial equivalence claim for the new measurement aggregation method of the subject device.

## Substantial Equivalence

The subject device is substantially equivalent to AUDICOR CPAM with SDB (K131883).

The non-clinical and clinical testing results demonstrates the subject device is as safe and effective as the predicate device noted.