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

May 1, 2015

toSense, Inc.
Nandini Murthy
Regulatory Consultant to toSense, Inc
4225 Executive Square, Suite 570
La Jolla, California 92037

Re: K142087
Trade/Device Name: Cova Monitoring System
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DSB, FLL
Dated: April 1, 2015
Received: April 2, 2015

Dear Nandini Mirthy,

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.

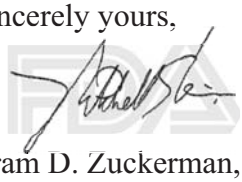
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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,



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

Enclosure

Section 4

Indications for Use Form

510(k) Number (if known): ___K142087_____

Device Name: ___CoVa™ Monitoring System___

Indications for Use:

The CoVa™ Monitoring System is intended for use under the direction of a licensed medical professional by adult patients at home to record, store, and transmit the following physiological data: i) Heart Rate including Heart Rate Variability; ii) Thoracic Impedance; iii) Respiration Rate; and iv) Posture. The CoVa™ Monitoring System only displays these physiological data to licensed medical professionals.

The CoVa™ Monitoring System is indicated for patients: i) with fluid-management problems; ii) taking diuretic medication; iii) living with heart failure; iv) living with end-stage renal disease; v) recovering from a coronary artery disease-related event; and/or vi) suffering from recurrent dehydration.

Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND	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)

510(k) Summary

Date prepared	May 1, 2015
Name	toSense, Inc. 4225 Executive Square Suite 570 La Jolla, CA 92037 (619) 733-4968
Contact Person	Matthew Banet, Ph.D. Chief Technology Officer
Trade Name	CoVa™ Monitoring System
Common Name	Mobile patient monitoring system, cardiac monitor
Classification Name	Patient Physiological Monitor (without arrhythmia detection or alarm); Impedance Plethysmograph
Classification Regulations	21 CFR 870.2300 (MWI), 21 CFR 870.2770 (DSB), 21 CFR 880.2910 (FLL)
Predicate Devices	Zoe Fluid Status Monitor (referred to herein as the 'Zoe monitor') Manufacturer: Non-Invasive Technologies, Inc. Number: K042113 Clearance Date: September 14, 2004 Avivo Mobile Patient Management System (referred to herein as the 'Corventis monitor') Manufacturer: Corventis Number: K113187 Clearance Date: January 4, 2012 ViSi Mobile Monitoring System (referred to herein as the 'ViSi monitor') Manufacturer: Sotera Wireless Number: K112478 Clearance Date: March 22, 2012
Description	toSense's CoVa™ Monitoring System features a body-worn Sensor, Gateway, and Web-based System. The Sensor non-invasively measures heart rate (HR), heart rate variability (HRV), respiration rate (RR), and thoracic index (TI). To determine these parameters, the Sensor measures and processes single-lead electrocardiogram (ECG) and thoracic bioimpedance (TBI) waveforms. Additionally, the Sensor measures skin temperature (TEMP) and posture using, respectively, a temperature sensor and accelerometer. The Sensor has a form factor similar to a conventional necklace, with all measurement electronics built into its strands and base. A pair of customized disposable Electrodes, each featuring two electrode regions, snaps into a magnetic interface on the backside of the base, and then attaches to the patient's chest to make a measurement. The Sensor is designed for measurement periods less

than about 5 minutes.

Using a Bluetooth transceiver, the Sensor wirelessly transmits information it measures from the patient to a Gateway, which can be a tablet computer or mobile phone running the Android operating system. Each of these systems receives information from the Sensor, and then forwards it to a Web-based System through either a local-area network (e.g., network based on 802.11), or a wide-area cellular network (e.g. AT&T). The Web-based System displays information, and can also forward it to a third-party system through a web-services interface.

Indications for Use

The CoVa™ Monitoring System is intended for use under the direction of a licensed medical professional by adult patients at home to record, store, and transmit the following physiological data: i) Heart rate including heart rate variability; ii) Respiration rate; iii) Thoracic impedance; and iv) Posture. The CoVa™ Monitoring System only displays these physiological data to licensed medical professionals.

The CoVa™ Monitoring System is indicated for patients: i) with fluid-management problems; ii) taking diuretic medication; iii) living with heart failure; iv) living with end-stage renal disease; v) recovering from coronary artery disease-related event; and/or vi) suffering from recurrent dehydration.

The following are the contraindications for the CoVa™ Monitoring System:

- The System is not to be used on patients with implanted cardiac devices, such as pacemakers and implanted cardio-defibrillators (ICDs).
- The System is not defibrillator-proof. Thus the sensor should be removed from a patient before using an external defibrillator.
- The System includes magnetically active materials, and thus should not be used by patients undergoing a procedure involving magnetic resonance imaging (MRI).

Summary of Substantial Equivalence

Each indication for use and measurement assigned to the CoVa™ Monitoring System is also assigned to one or more of the Corventis, Zoe, or ViSi monitors. The System's proposed intended-use population is also aligned with that of one or more of the predicate monitors.

The Sensor, along with the Zoe and Corventis monitors, all use an impedance-based technology to measure TI or an equivalent thereof. Our validations efforts, which compare the Sensor's measurements of TI to those made by a FDA-cleared reference device, indicate that measurements of TI made by these systems are substantially equivalent.

Both the Sensor and the Corventis monitors use the same impedance-based technology to measure RR. Our validations efforts, which compare the Sensor's measurements of RR to those made by a FDA-cleared reference device, indicate that measurements of RR made by these systems are substantially equivalent.

Both the Sensor and the Corventis monitor use standard technologies to measure ECG waveforms and, from these, calculate HR and HRV. The Sensor and the Corventis monitor also both use conventional tri-axial accelerometer sensors to measure motion-related properties of the patient, such as posture. The Sensor and the Corventis monitor both use a conventional Bluetooth wireless transceiver to send numerical and waveform information to a gateway device. And our Gateway and that used with the Corventis monitor both use a cellular transmitter or, alternatively, 802.11 to send information to a web-based system. Based on this, we do not believe our core technologies outside of those used for TI and RR raise any new questions of safety or effectiveness.

The Sensor measures TEMP with a thermal sensor in electrical contact with one of the Electrodes. During a measurement, the Electrode adheres to the patient's underlying skin, and within a few

minutes these components reach a thermal equilibrium. After this point the thermal sensor measures TEMP. The ViSi monitor measures skin temperature in a nearly identical manner using a small plastic component in its chest-worn sensor. Based on the commonality of these approaches, we do not believe our core technology for measuring TEMP raises any new questions of safety or effectiveness.

The Sensor, when compared to both the Corventis and Zoe monitors, has a different form factor and electrode configuration, and uses a different mechanism for securing its Electrodes. The Corventis monitor features a single, integrated patch with four electrode regions. The Zoe monitor features a remote, stand-alone console that connects to a pair of dual-region, body-worn electrodes through a pair of cables. The cables feature standard mechanical snaps to connect the electrodes. The console contains all measurement and data-processing electronics. The Zoe monitor is typically used daily and resides with the patient.

In contrast, the Sensor is shaped like a conventional necklace, and drapes around the patient's neck during a measurement. It is designed for one-time, daily use, and typically resides permanently with the patient. 2 disposable Electrodes, each containing 2 electrode regions, connect through a magnetic interface to the Sensor's base, and then attach to the patient. The Sensor's necklace-shaped form factor ensures that, on a daily basis, the Electrodes are positioned consistently on the patient.

Thus, we believe the mechanical differences between the Sensor and its predicates –i.e. the necklace-shaped form factor and the mechanism in which it supports electrodes– do not raise any new questions of safety.

Clinical and Non-Clinical Testing

toSense studied the CoVa™ Monitoring System (the test device) and its measurement of thoracic impedance with a clinical trial featuring 33 subjects receiving chronic maintenance hemodialysis and, in some cases, suffering from congestive heart failure. Table 1, below, refers to this study as 'Clinical Study 1'. Measurements were made on all subjects while they were receiving hemodialysis. The trial compared thoracic impedance measured with the test device to a similar impedance parameter measured simultaneously by a FDA-cleared reference device. Trained personnel applied both test and reference devices to subjects. Table 1 summarizes the comparison of the test and reference devices' impedance values using the rank-regression method, as investigated during Clinical Study 1. Additional analysis demonstrated an average Pearson's correlation between the test device's measurement of impedance and fluid removed by a machine performing the hemodialysis of $r = 0.93$ ($p < 0.0001$), and that the test device's measurement sensitivity was 1.72 Ohms/Liter. Studies estimate the test device's measurement precision for thoracic impedance when used for long-term monitoring, as calculated from the standard deviation of repeated measurements, may be in the order of magnitude of 1~2 Ohms. Separate studies estimate the test device's measurement precision for thoracic impedance when used for short-term monitoring, calculated in a similar manner, may be less than 1 Ohm.

toSense also studied the test device's measurement of thoracic impedance with a clinical trial featuring 23 subjects, all having fluid-management issues, such as congestive heart failure. Table 1 refers to this study as 'Clinical Study 2'. Here, both test and reference devices measured impedance values daily in the home environment over an extended period of time. Trained personnel applied the reference device to all subjects. In some cases, trained personnel also applied the test device; in others, the subjects applied the test device. Table 1 summarizes the comparison of the test and reference devices' impedance values using the rank-regression method, as investigated during Clinical Study 2.

toSense also studied the test device and its measurement of respiration rate with a clinical trial featuring 19 adult subjects undergoing breathing patterns with variable rates and tidal volumes that

simulate those encountered by intended-use populations. Table 1 refers to this study as 'Clinical Study 3'. The trial compared respiration rate values measured simultaneously with: 1) the test device; 2) a FDA-cleared monitor based on impedance pneumography (acceptance-standard device); and 3) a FDA-cleared monitor that measures end-tidal carbon dioxide and spriometry (reference device). Table 1 summarizes the comparison of the test and reference devices' impedance values using the rank-regression method, as investigated during Clinical Study 3.

Finally, toSense studied the test device's measurement accuracy of thoracic impedance, respiration rate, heart rate, heart rate variability, and skin temperature using bench studies featuring calibrated simulators. Table 1 refers to these studies as 'Clinical Studies 4a-e', respectively. Analysis of results from these studies, as determined using a standard regression model, are included in Table 1.

Clinical Study	Parameter Evaluated	N	Subject Type	Slope from Regression Model	Intercept from Regression Model
1	TI (compared to reference device)	33 subjects, 13 test devices, 500 measurements	undergoing chronic hemodialysis; may have CHF	0.86	35.8
2	TI (compared to reference device)	23 subjects, 2 test devices, 560 measurements	fluid-management issues	0.65	117
3	RR (compared to reference device)	19 subjects, 2 test devices, 682 measurements	healthy volunteers using breathing patterns encountered by intended-use populations	1.00	1.62
4a	TI (absolute accuracy)	8 devices, 88 measurements	simulator	1.00	0.09
4b	RR (absolute accuracy)	1 device, 15 measurements	simulator	1.02	-0.60
4c	HR (absolute accuracy)	1 device, 67 measurements	simulator	1.00	-0.41
4d	HRV (absolute accuracy)	1 device, 15 measurements	simulator	1.02	-2.53
4e	TEMP (absolute accuracy)	1 device, 40 measurements	simulator	0.99	0.35

Table 1: Summary of regression results for CoVa's measurements, as determined by Clinical Studies 1-4.

Performance

Components of the CoVa™ Monitoring System have been tested and meet the requirements of the

Testing

relevant sections of the following performance standards:

IEC 60601-1 Standard: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (2005)

IEC 60601-1-2 Standard: Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance, Collateral Standard: Electromagnetic Compatibility (2007)

60601-1-6 Standard: Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance, Collateral Standard: Usability; and IEC 62366 Standard: Medical Devices – Application of Usability Engineering to Medical Device

AAMI/ANSI EC13: Cardiac monitors, heart rate meters, and alarms (2002)

ISO 80601-2-56 Medical electrical equipment – Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurements

Conclusion

The CoVa™ Monitoring System has been tested and found to comply with recognized performance, safety, and electromagnetic compatibility standards for medical devices. Clinical studies indicate its measurements are substantially equivalent to those made by its predicate devices.

Based on the above, we believe the CoVa™ Monitoring System is as safe and effective as its predicate devices.