Non-Confidential Summary of Safety and Effectiveness
Page 1 of 4
19-Dec-08

MAR 2 3 2009

Inspired Technologies, Inc.
1061 Main Street - #24
N. Huntingdon, PA 15642

Tel - 724-861-5510
Fax - 724-861-5530

Official Contact: Rick Confer – Director RA/QA

Proprietary or Trade Name: CODR Model 300-CR

Usual Name: breathing frequency monitor

Classification Name: breathing frequency monitor
MNR – 868.2375

Predicate Devices: K051313 – Salter BiNAPS
K061996 – EB Neuro – Sandman

Device Description:
The Inspired Technologies Clinical Oxygen Dose Recorder (CODR) Model 300 CR is a portable data gathering and information display system which is intended to be used as an adjunct to commercially available pulse oximetry and oxygen delivery systems to enable the clinician to record and view the gathered data together.

The CODR records heart rate and oxygen saturation data provided by a cleared Pulse Oximetry system, flow and pressure data from the oxygen delivery system, and tracks breath rate and inhale/exhale ratio (I:E ratio) by monitoring the flow in the oxygen delivery tubing. The CODR displays this data in real time to enable the clinician to view the effects of the oxygen device's delivery performance on a patient as they rest and exercise. It is not to be used as a diagnostic tool. The CODR is intended to be used by trained clinicians in the hospital, clinical or home care environments.

The CODR consists of two components; (1) an interface module and (2) PC based data display software.

1. The interface module is a portable, battery powered module which is in line with Oxygen Source and is used to connect various oxygen sources, including LOX portables, standard oxygen cylinders, and oxygen concentrators. Standard, commercially available, single or dual lumen nasal cannula can be used with the interface module. The CODR interface module also has capability of connecting a Pulse Oximeter. The interface module is designed to be worn by the patient during evaluation of the system. It is approximately 6" X 4" X 2" deep and contains the pressure and flow sensors, a connector for the pulse oximeter, and a Secure Digital (SD) card slot for use in data recording. The interface module is powered by four AA batteries. Either alkaline or rechargeable batteries can be used.
2. The PC based data display software

Non-Confidential Summary of Safety and Effectiveness

19-Dec-08

Indications for Use:
The Clinical Oxygen Dose Recorder (CODR) Model 300-CR records heart rate and oxygen saturation data provided by a Pulse oximeter; flow and pressure data from the oxygen delivery system; and measures breath rate and inhale/exhale ratio (I:E ratio) by monitoring the flow in the oxygen delivery tubing. Data is presented to enable the clinician to view the effects of the oxygen device's delivery performance on a patient in different ambulatory settings, i.e., rest and exercise. It is not to be used as a diagnostic tool.

The CODR is intended to be used by trained clinicians in the hospital, clinical or home care environments.

For the patient population the CODR will have the same indications for use as the oxygen source to which it is attached.

Patient Population:
For the patient population the CODR will have the same indications for use as the oxygen source to which it is attached.

Environment of Use:
Hospital, clinical or home care

Contraindications:
None

Performance testing to support substantial equivalence:

Performance and verification / validation testing was performed with various pulse oximeters and oxygen source systems. These tests included:

- Accuracy of data measured
- Data transmission / collection accuracy
- EMC / EMI
- Mechanical and environmental testing

In all cases the CODR meet the specified performance criteria and was found to be substantially equivalence to the predicates.

Non-Confidential Summary of Safety and Effectiveness
Page 3 of 4
19-Dec-08

Features	Proposed Device CODR	Predicate -EB Neuro Sandman K061996	Predicate - Salter BiNAPS K051313
Indications for use	The Clinical Oxygen Dose Recorder (CODR) Model 300-CR records heart rate and oxygen saturation data provided by a Pulse oximeter; flow and pressure data from the oxygen delivery system; and measures breath rate and inhale/exhale ratio (I:E ratio) by monitoring the flow in the oxygen delivery tubing. Data is presented to enable the clinician to view the effects of the oxygen device's delivery performance on a patient in different ambulatory settings, i.e., rest and exercise. It is not to be used as a diagnostic tool.	Intended to collect physiological data to be used in PSG and sleep disorder studies.	Is an accessory intended for use with PSG equipment during sleep disorder studies for the purpose of detecting and amplifying breathing signals and detection of snoring of a sleeping patient
Environment of Use	Hospital, health care facilities, home care	Hospital, health care facilities, home care	Hospital, health care facilities, home care
Patient Population	For the patient population the CODR will have the same indications for use as the oxygen source to which it is attached.	Pediatric to adults	Not specified
Contraindications	None	None	None
Software driven	Yes	Yes	Yes
Components	Interface module – collects data Data display software Sensors Nasal cannula to patient Oxygen tubing from oxygen source Pulse Oximeter	Interface module – collects data Recorder unit Sensors Pulse oximeter	Interface module Nasal cannula
Prescriptive	Yes	Yes	Yes
Communication interface	Physiological data from pulse oximeter and sensors Measures parameters from the oxygen source	Physiological data from pulse oximeter and sensors	Physiological data from pulse oximeter and sensors

Non-Confidential Summary of Safety and Effectiveness
Page 4 of 4
19-Dec-08

Features	Proposed Device CODR	Predicate -EB Neuro Sandman K061996	Predicate - Salter BiNAPS K051313
Data recording	SD card and PC file	Internal flash chip	Not specified
Configuration	Wearable	Wearable	Not specified
Power	Battery	Battery	Battery
Sensors	Commercially available	Commercially available	Not specified
Patient interface	Nasal cannula	Electrodes	Nasal cannula
Data recorded	SpO_2 Flow Pressure Breathe rate I:E ratio	SpO_2 Flow Pressure Breathe rate	Flow Pressure Breathe rate
Connects to	Cleared pulse oximeter	Cleared pulse oximeter	Not specified
Alarms	None	None	None

Differences Between Other Legally Marketed Predicate Devices:

The proposed device is viewed as substantially equivalent to the predicate devices, K051313 and K061996.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2009

Inspired Technologies, Incorporated
C/o Mr. Paul Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134

Re: K082853
Trade/Device Name: Clinical Oxygen Dose Recorder (CODR) Model 300-CR
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: MNR
Dated: February 24, 2009
Received: February 26, 2009

Dear Mr. Dryden:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Ginette Y. Michaud, M.D.
Acting 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 Statement

510(k) Number: K082853

Device Name: Clinical Oxygen Dose Recorder (CODR) Model 300-CR

Indications for Use:

The Clinical Oxygen Dose Recorder (CODR) Model 300-CR records heart rate and oxygen saturation data provided by a Pulse oximeter; flow and pressure data from the oxygen delivery system; and measures breath rate and inhale/exhale ratio (I:E ratio) by monitoring the flow in the oxygen delivery tubing. Data is presented to enable the clinician to view the effects of the oxygen device's delivery performance on a patient in different ambulatory settings, i.e., rest and exercise. It is not to be used as a diagnostic tool.

The CODR is intended to be used by trained clinicians in the hospital, clinical or home care environments.

For the patient population the CODR will have the same indications for use as the oxygen source to which it is attached.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K082853