K130036

JAN 14 2014

5.0 510(k) Summary

Submitter:	Capnia, Inc. 2445 Faber Place, Suite 250 Palo Alto CA 94303 (650) 213-8444 phone (650) 213-8383 fax
Contact Person:	Julie Blacklock Director Quality and Regulatory Affairs (650) 213-8444 ext 41 julie@capnia.com
Date Prepared:	01/13/2014
Trade Name:	CoSense™ ETCO Monitor
Common Name:	Carbon Monoxide Monitor
Classification Name:	Carbon Monoxide Gas Analyzer (21 CFR 868.1430, Product Code CCJ)
Predicate Devices:	CoSense™ CO Monitor (K121768) and CO-STAT™ End Tidal Breath Analyzer (K974805) (reference predicate)
Device Description:	The CoSense ETCO Monitor is a battery-operated carbon monoxide (CO) monitor. It uses an infrared capnometer to detect the end-tidal portion of the breath and an electrochemical carbon monoxide sensor to measure the end-tidal breath CO concentration. The device consists of a portable unit with software controlled menu (date, time, patient identification, measurement time of monitoring), single-use nasal cannula, replaceable CO Sensor, and a battery charger/power supply.

Indications for Use:

The CoSense ETCO Monitor is indicated for the monitoring of carbon monoxide from endogenous sources (including hemolysis) and exogenous sources (including CO poisoning and smoke inhalation) in exhaled breath. The end tidal carbon monoxide level can be used for the monitoring of carbon monoxide in medical conditions in which the rate of hemolysis may be relevant. It is also for use in smoking cessation programs and can be used for the screening of CO poisoning and smoke inhalation.

Technological Characteristics:

The CoSense ETCO Monitor uses the identical performance specifications (accuracy, range, and resolution), software algorithms, sensors, and accessories as our predicate device, the CoSense CO Monitor. The CoSense ETCO Monitor also has similar performance specifications (accuracy, range, and resolution) as the reference predicate, CO-STAT End Tidal Breath Analyzer.

Comparison to Predicate Device (K121768) and Reference Predicate (K974805):

	Capnia CoSense ETCO Monitor (Subject Device)	**Capnia CoSense CO Monitor (Predicate Device)**	**Natus CO-STAT End Tidal Breath Analyzer (Reference Predicate Device)**
510(k) Number	K130036	K121768	K974805
Manufacturer	Capnia, Inc.	Capnia, Inc.	Natus Medical, Inc.
Classification	Class II	Class II	Class II
Product Code	CCJ	CCJ	CCJ
Regulation	21 CFR 868.1430	21 CFR 868.1430	21 CFR 868.1430
Indications for Use	The CoSense ETCO Monitor is indicated for the monitoring of carbon monoxide from endogenous sources (including hemolysis) and exogenous sources	The CoSense CO Monitor is indicated for the monitoring of Carbon Monoxide from endogenous and exogenous sources in exhaled breath. It is for use in smoking	The Natus Breath Analyzer is intended for non-invasive, quantitative measurement of respiratory rate, end tidal carbon dioxide concentration, and end tidal carbon monoxide (corrected for background

	Capnia CoSense ETCO Monitor (Subject Device)	Capnia CoSense CO Monitor (Predicate Device)	Natus CO-STAT End Tidal Breath Analyzer (Reference Predicate Device)
	(including CO poisoning and smoke inhalation) in exhaled breath. The end tidal carbon monoxide level can be used for the monitoring of carbon monoxide in medical conditions in which the rate of hemolysis may be relevant. It is also for use in smoking cessation programs and can be used for the screening of CO poisoning and smoke inhalation.	cessation programs and can be used for the screening of CO poisoning and smoke inhalation. It is for use by health professionals.	carbon monoxide) concentration in the breath. The analyzer is intended for use with neonates, children, and adults breathing spontaneously. The analyzer measures the carbon monoxide concentration in end tidal breath, as an indicator of the blood level of COHb. The level of COHb (and consequently the concentration of carbon monoxide in the end tidal breath) can be affected by endogenous sources (for example the rate of hemolysis), exogenous sources (for example, combustion engine exhaust), or in some cases both. The COHb level, elevated or normal, can be used in the diagnosis of medical conditions in which the rate of hemolysis may be relevant, and in the monitoring of patient populations affected by the rate of hemolysis. The analyzer is also indicated for use in respiratory status evaluation, whenever measurement of respiratory rate and end tidal carbon dioxide concentration are desired. The analyzer is intended for use under the direction of a physician in hospitals and a variety of health care settings.

	Capnia CoSense ETCO Monitor (Subject Device)	Capnia CoSense CO Monitor (Predicate Device)	Natus CO-STAT End Tidal Breath Analyzer (Reference Predicate Device)
Patient Interface	Nasal cannula	Nasal cannula	Nasal cannula
Dimensions (LxWxH)	246mm x 197mm x 68mm	244mm x 183mm x 58mm	222mm x 292mm x 152mm
Weight	3.3lbs	2.3lbs	12lbs
Materials			
CO Sensor Cell Type	Electrochemical	Electrochemical	Electrochemical
Cannula	Non-DEHP PVC	Non-DEHP PVC	Not Available
Battery	Li-Ion	Li-Ion	AC Power connected to UPS
Performance Specifications			
Accuracy	+/- 10% or +/-0.5ppm whichever is greater	+/- 10% or +/-0.5ppm whichever is greater	+/- 10% or +/-0.3ppm (whichever is greater) at 8-60 bpm
CO Measurement Range	1.0 – 25.0ppm	1.0 – 25.0ppm	0-25 ppm
Resolution	0.1 ppm	0.1 ppm	0.1 ppm
Measurement Time	Less than 5 minutes	Less than 5 minutes	90% of final reading in 30 seconds; total time unknown
Sample Collection	Collection of a normal breath using a disposable nasal cannula	Collection of a normal breath using a disposable nasal cannula	Collection of a normal breath using a disposable nasal cannula
Modes	Expired	Expired	Expired
Device Shelf Life	1 year before servicing	1 year before servicing	1 year before servicing
CO Sensor Shelf Life	6 months	6 months	30 days before calibration
Cannula Shelf Life	8 months	8 months	Not Available
Screen	LCD	LCD	Not Available
Software/ Hardware	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor	Not Available

	Capnia CoSense ETCO Monitor (Subject Device)	Capnia CoSense CO Monitor (Predicate Device)	Natus CO-STAT End Tidal Breath Analyzer (Reference Predicate Device)
Power Source	Rechargeable Battery	Rechargeable Battery	AC

Non-clinical Performance Data: The design and performance specifications are identical to our predicate device. No additional non-clinical performance data is provided.

Clinical Performance Data: An analysis of published clinical data was conducted. This analysis was performed on the uses of other FDA-cleared CO monitoring devices for measurement of CO in screening of CO poisoning, smoke inhalation and detection of hemolysis. Results provide objective evidence that the functional and performance specifications of CoSense device are similar to the devices in the published studies, specifically the CO-STAT End Tidal Breath Analyzer, and are within the range of accuracy, measurement, and resolution of the devices currently used clinically for detection of endogenous and exogenous sources of elevated CO.

Conclusion: Capnia considers the revised CoSense ETCO Monitor device to be equivalent to our predicate device and the reference predicate listed above. This conclusion is based upon the devices' similarities in indications for use and identical principles of operation, technology, and performance. The accuracy, measurement range, and resolution specifications are unchanged from our predicate CoSense device. These performance specifications are similar to the CO-STAT End Tidal Breath Analyzer (reference predicate). The proposed CoSense device indication is also similar to the indication for CO-STAT End Tidal Breath Analyzer, as both indications use hemolysis as examples of endogenous CO. Published clinical data and previous design verification data demonstrate that the device is equivalent to our predicate device.

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

January 14, 2014

Capnia, Incorporated
Ms. Julie Blacklock
Director, Quality and Regulatory Affairs
2445 Faber Place, Suite 250
Palo Alto, CA 94303

Re: K130036
Trade/Device Name: CoSense™ ETCO Monitor
Regulation Number: 21 CFR 868.1430
Regulation Name: Carbon Monoxide Gas Analyzer
Regulatory Class: II
Product Code: CCJ
Dated: December 13, 2013
Received: December 16, 2013

Dear Ms. Blacklock:

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.

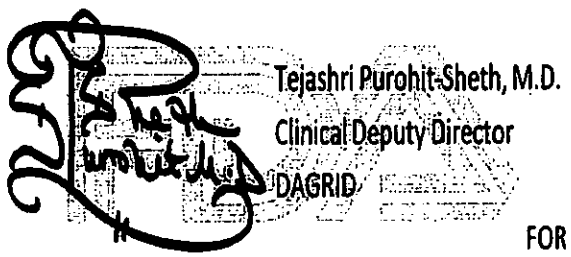
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

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 on last page.

510(k) Number *(if known)*

K130036

Device Name

CoSense ETCO Monitor

Indications for Use *(Describe)*

The CoSense ETCO Monitor is indicated for the monitoring of carbon monoxide from endogenous sources (including hemolysis) and exogenous sources (including CO poisoning and smoke inhalation) in exhaled breath. The end tidal carbon monoxide level can be used for the monitoring of carbon monoxide in medical conditions in which the rate of hemolysis may be relevant. It is also for use in smoking cessation programs and can be used for the screening of CO poisoning and smoke inhalation.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Nayan J. Patel -S
2014.01.13 18:05:50 -05'00'

4-2

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."