



Food and Drug Administration  
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July 22, 2015

Capnia, Inc.  
Kristen Yen  
Vice President, Clinical and Regulatory Affairs  
3 Twin Dolphin Drive, Suite 160  
Redwood City, CA 04065

Re: K151107  
Trade/Device Name: CoSense ETCO Monitor  
Regulation Number: 21 CFR 868.1430  
Regulation Name: Carbon Monoxide Gas Analyzer  
Regulatory Class: Class II  
Product Code: CCJ  
Dated: June 19, 2015  
Received: June 22, 2015

Dear Ms. Kristen Yen:

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.*

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Enclosure

## Indications for Use

510(k) Number (if known)

K151107

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)

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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## 510(k) Summary

<b>Submitter:</b>	Capnia, Inc. 3 Twin Dolphin Drive, Ste 160 Redwood City, CA 94065
<b>Contact Person:</b>	Kristen Yen Vice President, Clinical and Regulatory Affairs Tel: (650) 353-2051 Fax: (650) 213-8383 Email: kristen@capnia.com
<b>Date Prepared:</b>	7/21/2015
<b>Trade Name:</b>	CoSense® ETCO Monitor
<b>Common Name:</b>	Carbon Monoxide Monitor
<b>Classification Name:</b>	Carbon Monoxide Gas Analyzer (21 CFR 868.1430, Product Code CCJ)
<b>Predicate Device:</b>	CoSense® ETCO Monitor (K130036)
<b>Device Description:</b>	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.
<b>Indication for Use:</b>	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.
<b>Technological Characteristics:</b>	The CoSense ETCO Monitor uses the identical performance specifications (accuracy, range, and resolution), related software algorithms, sensors, and accessories as our predicate device, the CoSense ETCO Monitor.

## Comparison to Predicate Device (K130036)

	Capnia CoSense ETCO Monitor (Subject Device)	Capnia CoSense ETCO Monitor (Predicate Device)
<b>510(k) Number</b>		K130036
<b>Manufacturer</b>	Capnia, Inc.	Capnia, Inc.

	<b>Capnia CoSense ETCO Monitor (Subject Device)</b>	<b>Capnia CoSense ETCO Monitor (Predicate Device)</b>
<b>Classification</b>	Class II	Class II
<b>Product Code</b>	CCJ	CCJ
<b>Regulation</b>	21 CFR 868.1430	21 CFR 868.1430
<b>Indications for Use</b>	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.	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.
<b>Patient Interface</b>	Nasal cannula	Nasal cannula
<b>Dimensions (LxWxH)</b>	246mm x 197mm x 68mm	246mm x 197mm x 68mm
<b>Weight</b>	3.3lbs	3.3lbs
<b>Materials</b>		
<b>CO Sensor Cell Type</b>	Electrochemical (heating element in sensor housing)	Electrochemical
<b>Cannula</b>	Non-DEHP PVC	Non-DEHP PVC
<b>Battery</b>	Li-Ion	Li-Ion
<b>Performance Specifications</b>		
<b>Accuracy</b>	+/- 10% or +/-0.5ppm whichever is greater	+/- 10% or +/-0.5ppm whichever is greater
<b>CO Measurement Range</b>	1.0 – 25.0ppm	1.0 – 25.0ppm
<b>Resolution</b>	0.1 ppm	0.1 ppm
<b>Breaths per Minute</b>	10 – 50 bpm	10 - 50 bpm
<b>Sample Collection Rate</b>	48 mL/min $\pm$ 2.0 mL/min	48 mL/min $\pm$ 2.0 mL/min

	<b>Capnia CoSense ETCO Monitor (Subject Device)</b>	<b>Capnia CoSense ETCO Monitor (Predicate Device)</b>
<b>Measurement Time</b>	Less than 5 minutes	Less than 5 minutes
<b>Sample collection</b>	Collection of a normal breath using a disposable nasal cannula	Collection of a normal breath using a disposable nasal cannula
<b>Modes</b>	Expired	Expired
<b>Device shelf life</b>	1 year before servicing	1 year before servicing
<b>CO Sensor shelf life</b>	6 months	6 months
<b>Cannula shelf life</b>	13 months	8 months
<b>Screen</b>	LCD	LCD
<b>Software/ Hardware</b>	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor
<b>Rechargeable Battery</b>	Yes	Yes
<b>Power Source</b>	Rechargeable Battery	Rechargeable Battery
<b>Functional and Safety Testing:</b>	<p>The design and performance specifications are identical and unchanged from our predicate device. To verify that the device design met its functional and performance requirements, representative samples of the device underwent biocompatibility (Cytotoxicity, Sensitization, and Irritation), software, electrical, and mechanical testing, specifically CO Measurement accuracy. The following industry standards were used in applicable tests:</p> <ul style="list-style-type: none"> <li>• AAMI / ANSI / ISO 10993-1 2009/(R) 2013 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process</li> <li>• AAMI / ANSI / ISO 10993-5 2009/(R) 2014 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity</li> <li>• AAMI / ANSI / ISO 10993-10 2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization</li> <li>• General Principles of Software Validation; Final Guidance for Industry and FDA Staff</li> <li>• AAMI / ANSI / IEC 60601-1-2:2007 (R) 2012 Medical Electrical Equipment – Part 1-2: General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility</li> <li>• ASTM D4169-09 Standard Practice for Performance Testing of Shipping Containers and Systems</li> </ul>	

	<b>Capnia CoSense ETCO Monitor (Subject Device)</b>	<b>Capnia CoSense ETCO Monitor (Predicate Device)</b>
<b>Technical Comparison of Changes:</b>	<p>The modified CoSense ETCO Monitor is substantially equivalent to the predicate device. In accordance with the FDA Guidance document “Deciding When to Submit a 510(k) for a Change to an Existing Device”, the modifications were thoroughly reviewed for introduction of new risks. The differences between the subject device and predicate device (heating element, cannula configuration, flow rate sensor, and software updates) do not result in a change to performance specifications or intended use of the device.</p>	
<b>Conclusion:</b>	<p>Capnia considers the CoSense ETCO Monitor device to be substantially equivalent to our predicate device listed above. This conclusion is based upon the devices’ similarities in principles of operation, performance requirements, functional and safety testing as well as indications for use.</p>	