May 29, 2026

Capnia, Inc.
% Rob Packard
Senior Regulatory Consultant
Medical Device Academy, Inc.
345 Lincoln Hill Rd
Shrewsbury, Vermont 05738

Re: K253119
Trade/Device Name: CoSense ETCO Monitor (C20112)
Regulation Number: 21 CFR 868.1430
Regulation Name: Carbon Monoxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCJ
Dated: May 1, 2026
Received: May 1, 2026

Dear Rob Packard:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic.

See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley Q. Quinn -S

Bradley Quinn
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K253119

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 can be used with the pediatric population. 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.

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

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510(k) SUMMARY – K253119

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER INFORMATION 21 CFR 807.92(a)(1)

APPLICANT

Company Name:	Capnia, Inc.
Address:	1101 Chess Drive
City, State, Zip	Foster City, CA 94404
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Contact Name:	Ed Baumann
Contact Email:	ed.baumann@capnia.com

CORRESPONDENT

Company Name:	Medical Device Academy, Inc.
Address:	345 Lincoln Hill Road
City, State, Zip	Shrewsbury, VT 05738
Tel:	+1.802.258.1881
Contact Name:	Rob Packard, President
Contact Email:	rob@fdaestar.com

Date Prepared: May 26, 2026

II. NAME OF THE DEVICE 21 CFR 807.92(a)(2)

Device Trade Name:	CoSense ETCO Monitor
Classification Name:	Analyzer, gas, carbon-monoxide, gaseous-phase
Regulation:	21 CFR 868.1430
Regulatory Class:	Class 2
Device Panel:	Anesthesiology
Product Classification Code:	CCJ

III. IDENTIFICATION OF THE PREDICATE 21 CFR 807.92(a)(3)

Primary Predicate

Predicate Manufacturer:	Capnia, Inc.
Predicate Trade Name:	CoSense ETCO Monitor
Predicate 510(k):	K151107

No secondary predicate or reference device was used in this submission.

IV. DESCRIPTION OF THE DEVICE 21 CFR 807.92(a)(4)

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.

The front panel of the CoSense device contains the ON/OFF button and a touch screen display which contains the controls and indicators. The front panel includes the menu controls, battery status, time, date, sensor status, and options to select patient information and measurement results.

V. STATEMENT OF INTENDED USE 21 CFR 807.92(a)(5)

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 can be used with the pediatric population. It is also for use in smoking cessation programs and can be used for the screening of CO poisoning and smoke inhalation.

INDICATIONS FOR USE COMPARISON

The indications for use for the subject device are expanded to include the use for pediatric population. The difference is the patient population, and it is justified by the clinical data.

VI. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS 21 CFR 807.92(a)(6)

TECHNOLOGICAL COMPARISON

The subject device has the same technological characteristics (i. e., design, material, chemical composition, principle of operation, energy source etc.) as the predicate device as stated below:

- The dimensions of the subject device are 246mm x 197mm x 68mm that is the same as the predicate device.
- The weight of the subject device is 3.3lbs that is the same as the predicate device.
- The CO sensor cell type is electrochemical for both the subject device and the predicate device.
- The Cannula for both the subject and the predicate devices is made of Non-DEHP PVC.
- The battery type used for both the subject and the predicate devices is Li-Ion.

VII. SUBSTANTIAL EQUIVALENCE COMPARISON TABLE 21 CFR 807.92(a)(6)

The subject device CoSense ETCO Monitor is substantially equivalent to the predicate version. The following features are identical to those that previously received 510(k) clearance:

- Have the same intended use
- Use the same operating principle
- Incorporate the same basic design
- Incorporate the same materials
- Have the same shelf life
- Packaged using the same materials and processes

There are no changes in design characteristics from the previous device to the device in this application. The only change is the subject device's indications for use, expanding to include the pediatric population. The difference is the patient population, and it is justified by the clinical data.

Table 1: Comparison of CoSense ETCO Monitor (K253119) with CoSense ETCO Monitor (K151107).

	Capnia CoSense ETCO Monitor (Subject Device) K253119	**Capnia CoSense ETCO Monitor (Predicate Device) K151107**	**Justification for Differences**
510(k) Number	K253119	K151107	N/A
Manufacturer	Capnia, Inc.	Capnia, Inc.	Same as the predicate device.
Classification	Class II	Class II	Same as the predicate device.
Product Code	CCJ	CCJ	Same as the predicate device.
Regulation	21 CFR 868.1430	21 CFR 868.1430	Same as the predicate device.
Indications for Use	CoSense 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 can be used with the pediatric population. 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.	The indications for use for the subject device are expanded to include the pediatric population. The difference is the patient population, and it is justified by the clinical data.
Patient Interface	Nasal cannula	Nasal cannula	Same as the predicate device.
Dimensions (LxWxH)	246mm x 197mm x 68mm	246mm x 197mm x 68mm	Same as the predicate device.
Weight	3.3lbs	3.3lbs	Same as the predicate device.
Materials	N/A	N/A	N/A
CO Sensor Cell Type	Electrochemical	Electrochemical	Same as the predicate device.
Cannula	Non-DEHP PVC	Non-DEHP PVC	Same as the predicate device.
Battery	Li-Ion	Li-Ion	Same as the predicate device.

Performance Specifications	N/A	N/A	N/A
Accuracy	+/- 10% or +/-0.5ppm whichever is greater	+/- 10% or +/-0.5ppm whichever is greater	Same as the predicate device.
CO Measurement Range	1.0 – 25.0ppm	1.0 – 25.0ppm	Same as the predicate device.
Resolution	0.1 ppm	0.1 ppm	Same as the predicate device.
Breaths per Minute	10 – 50 bpm	10-50 bpm	Same as the predicate device.
Sample Collection Rate	48 mL/min $\pm$ 2.0 mL/min	48 mL/min $\pm$ 2.0 mL/min	Same as the predicate device.
Measurement Time	Less than 5 minutes	Less than 5 minutes	Same as the predicate device.
Sample collection	Collection of a normal breath using a disposable nasal cannula	Collection of a normal breath using a disposable nasal cannula	Same as the predicate device.
Modes	Expired	Expired	Same as the predicate device.
Device shelf life	7 years	7 years	Same as the predicate device.
CO Sensor shelf life	15 months	15 months	Same as the predicate device.
Cannula shelf life	5 years / 60 months	5 years / 60 months	Same as the predicate device.
Screen	LCD	LCD	Same as the predicate device.
Software/ Hardware	Analog and digital electronics with microprocessor	Analog and digital electronics with microprocessor	Same as the predicate device.
Rechargeable Battery	Yes	Yes	Same as the predicate device.
Power Source	Rechargeable Battery	Rechargeable Battery	Same as the predicate device.

VIII. BRIEF DISCUSSION OF NONCLINICAL TESTS 21 CFR 807.92(b)(1)

The following nonclinical testing was conducted to support the determination of substantial equivalence.

Biocompatibility Testing
• Cytotoxicity Testing (MEM Elution) - ISO 10993-5
• Sensitization Testing (Guinea Pig Maximization) - ISO 10993-10
• Irritation Testing - ISO 10993-10

Sterilization Validation
Not applicable, because the subject device and components are non-sterile and components are not intended to be sterilized by the user.

Shelf-life
Accelerated age testing in accordance with:
• ASTM F1980-16
• ASTM D4169-09

Software Validation, Cybersecurity, Wireless Safety, and Interoperability
Software validation was conducted in accordance with:
• IEC 62304
Cybersecurity, wireless safety, and interoperability testing are not applicable to the subject device.

Electrical Safety & EMC Testing
• IEC 60601-1-2
• IEC 60601-1

Performance Testing (non-clinical benchtop):
• Non-clinical performance testing was performed to verify CO measurement accuracy—including the revised indications for use.
• Usability Testing was performed to validate that usability risk controls implemented are effective for the revised indications for use.

Performance Testing (animal studies):
Not Applicable, because the device does not require animal studies to demonstrate performance.

IX. BRIEF DISCUSSION OF CLINICAL TESTS 21 CFR 807.92(b)(2)

The clinical testing is supported by peer-reviewed studies written by clinical experts.

X. CONCLUSIONS FROM NONCLINICAL AND CLINICAL TESTS

21 CFR 807.92(b)(3)

The subject device, CoSense ETCO Monitor (K253119), has equivalent indications for use when compared with the predicate device, CoSense ETCO Monitor (K151107). The subject device and the predicate device have the same technological characteristics. Both devices passed the same safety and performance testing. Non-clinical benchtop testing shows that the subject device is substantially equivalent in safety and effectiveness to the predicate device and performs as well as the predicate device.