OCT 3 1 2012

510(K) SUMMARY

Table 1: 510(k) Summary K121768

Submitter:	Capnia, Inc. 2445 Faber Place, Suite 250 Palo Alto CA 94303
Contact Person:	Julie Blacklock Associate Director, Regulatory Affairs and Quality Assurance (650) 213-8444 ext 41 julie@capnia.com
Date Prepared:	6/14/2012
Trade Name:	CoSense™ CO Monitor
Common Name:	Carbon Monoxide Monitor
Classification:	Class II
Product Code:	CCJ, 868.1430
Predicate Device(s):	The subject device is equivalent to the following devices: • FIM Medical Tabataba CO Tester (K080278)
Device Description:	The CoSense CO Monitor is a battery-operated carbon monoxide 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 power supply.
Indication for Use:	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 cessation programs and can be used for the screening of CO poisoning and smoke inhalation. It is for use by health professionals.

Functional and Safety Testing:	To verify that device design meets its functional and performance requirements, representative samples of the device underwent biocompatibility, software, electrical, and mechanical testing in accordance with the following industry standards: • AAMI/ANSI/ISO 10993-1:2009 Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process • General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Version January 11, 2002 • AAMI/ANSI/IEC 60601-1:1998 Medical Electrical Equipment—Part 1: General Requirements for Safety • AAMI/ANSI/IEC 60101-1-2:2001 Medical Electrical Equipment—Part 1-2: General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility • ASTM D4169-09 Standard Practice for Performance Testing of Shipping Containers and Systems
Conclusion:	Capnia considers the CoSense device to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in indications for use, principles of operation, technology, and materials.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 31 2012

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

Re: K121768
Trade/Device Name: Capnia CoSense CO Monitor
Regulation Number: 21 CFR 868.1430
Regulation Name: Carbon Monoxide Gas Analyzer
Regulatory Class: II
Product Code: CCJ
Dated: October 10, 2012
Received: October 11, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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

Anthony D. Watson, B.S., M.S., M.B.A.
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

Device Name: Capnia CoSense CO Monitor

Indications for Use:

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 cessation programs and can be used for the screening of CO poisoning and smoke inhalation. It is for use by health professionals.

Prescription Use ___X___ (21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 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: k217768