



Food and Drug Administration
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September 29, 2017

CARROT SENSE, INC.
C/O JONATHAN KAHAN
PARTNER
555 THIRTEENTH STREET NW
WASHINGTON DC 20004

Re: K171408
Trade/Device Name: Carbon Monoxide Breath Sensor System (COBSS)
Regulation Number: 21 CFR 868.1430
Regulation Name: Carbon monoxide gas analyzer
Regulatory Class: II
Product Code: CCJ
Dated: August 30, 2017
Received: August 30, 2017

Dear Jonathan Kahan:

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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), 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,

Kellie B. Kelm -S

for Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number (if known)
K171408

Device Name
Carbon Monoxide Breath Sensor System (COBSS)

Indications for Use (Describe)

The Carbon Monoxide Breath Sensor System (COBSS) is a breath carbon monoxide monitor intended for single-user use by cigarette smokers in smoking cessation programs to inform the user about how breath carbon monoxide levels are affected by smoking behavior. The device is not intended to be used with other inhaled products.

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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k171408

510(k) SUMMARY

Carrot Sense's Carbon Monoxide Breath Sensor System (COBSS)

Submitter

Company: Carrot Sense, Inc.
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Phone: (650) 520-3259
Contact Person: Daniel J Balbierz
Date Prepared: September 27, 2017

Subject Device

Name of Device: Carbon Monoxide Breath Sensor System (COBSS)
Classification Name: Carbon monoxide gas analyzer
Regulation: 21 C.F.R. § 868.1430
Regulatory Class: Class II
Product Code: CCJ

Predicate Device

Company: Bedfont Scientific LTD.
Device Name: Micro+ Smokerlyzer
510(k) Number: K082315
Regulation: 868.1430
Product Codes: CCJ

Device Description

The Carbon Monoxide Breath Sensor System (COBSS) is a breath carbon monoxide ("CO") monitor intended for single-user over-the-counter ("OTC") use by smokers in smoking cessation programs. The COBSS is a portable, battery-powered device that is composed of the following:

- **CO Breath Sensor.** A personal mobile breath sensor capable of measuring the level of CO in exhaled breath.
- **Breath Sensor App.** A smart phone app which displays the exhaled breath CO value to the user.

The CO Breath Sensor pairs to the Breath Sensor Application (“BSA”) on the smartphone via low-energy Bluetooth. Once paired, the CO Breath Sensor communicates exclusively with the user’s phone and is invisible to other devices. The primary screen for the BSA is the CO Log where the most recent exhaled breath CO value in parts-per-million (“ppm”) is displayed at the top of the screen. The CO measurements are color coded according to the CO level, and the length of the bar is associated with the ppm value to graphically show the user their relative levels of exhaled breath CO throughout the day and between days.

CO levels in exhaled breath of smokers correlate closely with smoking behavior, *i.e.*, intensity, frequency, and amount. Simply put, the more a person smokes, the higher their exhaled breath CO levels tend to be. Exhaled breath CO readings can inform the user about how breath carbon monoxide levels are affected by smoking behavior.

Intended Use / Indications for Use

The Carbon Monoxide Breath Sensor System (COBSS) is a breath carbon monoxide monitor intended for single user use by cigarette smokers in smoking cessation programs to inform the user about how breath carbon monoxide levels are affected by smoking behavior. The device is not intended to be used with other inhaled products.

Substantial Equivalence

The COBSS is substantially equivalent to Bedfont Scientific’s Micro+ Smokerlyzer (“Smokerlyzer”) cleared under 510(k) number K082315. Both devices have the same intended use of measuring breath CO levels of smokers in smoking cessation programs. Specifically, both the subject and the predicate devices provide breath CO measurements to inform the user about how breath carbon monoxide levels are affected by smoking behavior. The COBSS’ labeling provides a clear understanding of the CO measurements, appropriate precautions, and warnings. A combined human factors and comparative study demonstrated that lay users were able to adequately use the COBSS and to understand the CO measurements.

In addition, the COBSS has similar technological characteristics as the predicate device. Both are portable, battery powered devices that use electrochemical sensors to non-invasively monitor CO levels. The COBSS provides the CO measurements in a smartphone app, while the predicate uses a touch screen display. However, these minor differences in technological characteristics do not present any different issues of safety or effectiveness. In addition, analytical bench testing and the combined performance and human factors study demonstrated substantially equivalent performance between the subject and the predicate devices. Thus, the COBSS is substantially equivalent to the predicate device.

A substantial equivalence table summarizing the similarities and differences between the COBSS and the predicate device is provided in **Table 1**.

Table 1 – Comparison of Substantial Equivalence

Similarities

| Feature | Subject Device: Carrot Sense's COBSS | Predicate Device: Bedfont Scientific's Micro+ Smokerlyzer (K082315) |
|----------------------|--|--|
| Intended Use | Intended for single-user use by cigarette smokers in smoking cessation programs to inform the user about how breath carbon monoxide levels are affected by smoking behavior. | Intended for multipatient use by healthcare professionals in smoking cessation programs and as an indicator of Carbon Monoxide poisoning in healthcare environments. |
| Sensor Technology | Same | Electrochemical Sensor |
| Sensor Drift | Same | <5% per annum |
| H2 Cross Sensitivity | Same | <6% |

Differences

| Feature | Subject Device: Carrot Sense's COBSS | Predicate Device: Bedfont Scientific's Micro+ Smokerlyzer (K082315) |
|--------------------|--|---|
| Environment of Use | Over the counter, home | Prescription use only, healthcare |
| Design Features | <ul style="list-style-type: none"> • Non-invasively measures CO in exhaled breath • Hand-held battery powered • Visual and audible alarms | <ul style="list-style-type: none"> • Non-invasively measures CO in exhaled breath • Hand-held battery powered • Visual and audible alarms • Touch screen interface • No smartphone app |
| Power Source | Rechargeable lithium ion battery | 4.5V, 3 x AA/LR6 type battery |
| CO Measuring Range | 0 – 100 ppm | 0 – 250 ppm |
| Interfering Gases | Hydrogen | Hydrogen, Nitric Oxide, and Ethylene |

Bench Testing

The following summarizes the bench testing completed for the Carbon Monoxide Breath Sensor System:

- Sensor performance, including accuracy, precision, linearity, and H₂ Cross Sensitivity
- Interfering Gases
- Device Use Testing
- Shelf Life/Sensor Drift

Combined Human Factors and Comparative Performance Study

Carrot Sense conducted a combined human factors and comparative performance study to evaluate the following:

- **Human Factors:** Assess whether an untrained lay user group (representative of intended users) can operate the device and interpret the results correctly using the device labeling.
- **Comparative Performance:** Assess the correlation between the measured CO levels (in ppm) of the study CO breath sensor (Carrot Sense) submitted by a self-trained user without guidance by study personnel and the predicate CO breath sensor (Smokerlyzer) submitted with guidance by a health care professional trained in the use of the device.

The study was a prospective, open label, single center design and enrolled 70 lay users. Study participants comprised adult smokers, who represent the intended COBSS user profile. The study included two user groups (ages 18-49 years and 50-80 years). Study subjects participated in 60-90 minute study sessions that consisted of an introduction, simulated use, performance paired breath samples, user documentation assessment and subjective feedback and rating scales.

For the comparative performance portion of the study, the measurement of CO in exhaled breath by a lay user using COBSS without assistance was comparable to measurements obtained from the predicate device administered by trained personnel. On regression analysis, the 70 paired measurements of CO produced a line with a slope of 0.9289, a y-intercept of -0.0306 and a correlation coefficient of 0.9878. COBSS CO measurements agreed with the predicate device's category 91% (64/70) of the time. The COBSS CO level category agreed with the predicate's CO level category in 18/19 (95%) paired samples for the green category (0-6 ppm), 5/7 (71%) for the orange category (7-9 ppm), and 41/44 (93%) for the red category (10 ppm or greater). The human factors/usability portion of the study demonstrated that the device is safe and effective for the intended users, its intended uses, and use environments. All participants, overall, were observed to safely use all primary operating functions. There were no instances of close calls or observed hazard-related use scenarios that could have resulted in significant patient or user harm. Based on both objective and subjective input, the risk profile acceptability of the device was confirmed.

Overall, the combined human factors and comparative performance study demonstrated that lay users were able to use the COBSS safely and effectively for its intended use, and that the COBSS performance was acceptable when compared to the predicate device.

Conclusion

The COBSS is substantially equivalent to the predicate Smokerlyzer. Both devices have the same intended uses and similar indications, technological characteristics, and principles of operation. The differences in OTC indication do not alter the intended use of the device as a breath CO monitor for smoking cessation programs. In addition, minor technological differences between the COBSS and its predicate device do not raise different questions of safety or effectiveness. Bench testing and a combined human factors and comparative study demonstrated substantially equivalence performance. Furthermore, the study demonstrated that lay users were able to adequately use the COBSS and understand the CO measurements. Thus, the COBSS is substantially equivalent to the predicate device.