June 30, 2021

Carrot Inc.
% Jonathan Kahan
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K201206
Trade/Device Name: Pivot Breath Sensor
Regulation Number: 21 CFR 868.1430
Regulation Name: Carbon monoxide gas analyzer
Regulatory Class: Class II
Product Code: CCJ
Dated: October 13, 2020
Received: October 13, 2020

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. 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 located 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.

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

Marianela Perez-Torres, Ph.D.
Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201206

Device Name

Pivot Breath Sensor

Indications for Use *(Describe)*

The Pivot Breath Sensor is a breath carbon monoxide monitor intended for single-user use by cigarette smokers as an educational and motivational tool 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 combustible, 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.

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."

510(k) SUMMARY

Carrot Inc.'s Pivot Breath Sensor

I. Submitter

Company:	Carrot Inc.
Address:	1400A Seaport Blvd, Suite 501 Redwood City, CA 94063
Phone:	(717) 380-1196
Contact Person:	Sara Lippert
Date Prepared:	June 30, 2021

II. Subject Device

Company:	Carrot Inc.
Trade Name:	Carbon Monoxide Breath Sensor System
Model Name:	Pivot Breath Sensor
510(k) Number:	K201206
Classification Name:	Carbon monoxide gas analyzer
Regulation:	21 C.F.R. § 868.1430
Regulatory Class:	Class II
Product Code:	CCJ

III. Predicate Device

Company:	Carrot Inc.
Trade Name:	Carbon Monoxide Breath Sensor System
Model Name:	Carbon Monoxide Breath Sensor System
510(k) Number:	K171408
Classification Name:	Carbon monoxide gas analyzer
Regulation:	21 C.F.R. § 868.1430
Regulatory Class:	Class II
Product Code:	CCJ

IV. Device Description

The Pivot Breath Sensor is a personal, portable, lithium ion battery powered breath carbon monoxide ("CO") monitoring device that measures the level of CO in an individual's exhaled breath. It is intended for single-user over-the-counter ("OTC") use by cigarette smokers (users) to measure CO levels in their exhaled breath. This parameter correlates closely with carboxyhemoglobin levels and with cigarette smoking behavior. Hence, the more a person smokes, the higher are their exhaled breath CO levels.

The user submits a breath sample by exhaling (blowing) into the mouthpiece of the Pivot Breath Sensor which is directed over electrochemical sensors to quantify the CO level in the breath. The sensor has two buttons – a front, center button and a side button – to help with user inputs and navigation. It also has a rechargeable battery that can be charged using a micro-USB cable by plugging into USB compatible charging sources such as a computer, USB adapter for power outlet, or car USB port.

The calculated CO concentration/ level of the exhaled breath is displayed to the user in whole number parts-per-million ("ppm") on the LCD screen of the sensor. The Pivot breath sensor measures and displays CO concentrations from 0 to 100 ppm. Each of the breath sample results is shown to the user with a corresponding color and a number. The color is intended to aid in giving context to the quantitative CO value, aligning with the predicate device's color coding and scientific literature.

The sensor can display multiple samples as the CO log and helps to graphically show the user their relative levels of exhaled breath CO throughout the day and between days. Hence, periodic measurements of CO levels may provide users with feedback regarding their smoking exposure, thus helping them to become educated and motivated to quit smoking, as supported by reference literature.

V. Intended Use / Indications for Use

The Pivot Breath Sensor is a breath carbon monoxide monitor intended for single-user use by cigarette smokers as an educational and motivational tool 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 combustible, inhaled products.

VI. Summary of Performance Testing

The following tests were conducted to demonstrate the Pivot Breath Sensor's safety and effectiveness.

Bench Tests Performed	Results
Shelf Life	Passed with 18 month shelf life
Biocompatibility	Passed ISO-10993 tests for cytotoxicity, sensitization and irritation
Software Validation	Passed unit, integration and system testing of firmware
Wireless Coexistence	Passed requirements
EMC testing	Passed ISO 60601 testing requirements
Sensor Performance	Passed testing related to accuracy, precision, linearity and cross sensitivity. Testing included multiple lots at various temperature and humidity conditions.
Interfering Gases	Completed testing of interfering gases and included in labeling where applicable
Hardware Verification	Passed hardware and battery life related testing
Packaging Testing	Passed functionality testing after being subjected to ISTA 3A conditioning
Device Use Life	Passed long-term repeated use testing

	Clinical Studies		
Study Attribute	**18-RP-1061A (Human Factors)**	**18-RP-1062A (Comparative Performance)**	**20-RP-1083A (Expanded Indications)**
Objective	Assess whether an untrained lay user group (representative of intended users) can operate the device and interpret the results correctly using only the instructions that will be provided with the marketed device.	Assess correlation between the measured CO levels (in ppm) of the Pivot Breath Sensor submitted by a self-trained user without guidance by study personnel and the prescription-use CO breath sensor submitted with guidance by a trained health care professional.	Assess changes in attitudes and understanding towards quitting smoking as well as smoking behavior change with use of the Pivot breath sensor.
Study Design	Prospective, open label, single center	Prospective, open label, single center	Prospective, open label, single center
Subjects	15 subjects who self-report smoking 2 or more cigarettes each day	70 subjects who self-report smoking 2 or more cigarettes each day	234 subjects, in 2 cohorts: • 40-60% who self-report smoking 10-19 cigarettes per day (CPD) • 40-60% who self-report smoking 20 or more CPD
Success Criteria	Ensure that untrained lay users can properly operate the device, and can interpret the results correctly using only the labeling to be provided. Validate appropriate mitigations of use-related hazards identified in risk management documentation.	Based on the null hypothesis that the Pearson correlation coefficient of prescription device and Pivot Breath Sensor is 0.90 and the alternative hypothesis that it is >0.90, passing criterion is refuting the null hypothesis with a power of ≥90% assuming an 0.05 alpha level.	Primary endpoint will assess change in the proportion of participants' Stage of Change response at day 28 versus baseline. Secondary endpoints include: the proportion of participants who report ≥ 1 quit attempt by day 28, and the proportion of participants who reduce their CPD by ≥ 50% by day 28, compared to baseline.
Results	The Human Factors portion of the study found the device to be safe and effective for the intended users, uses, and use environments. All participants, overall, were observed to safely perform critical tasks.	Using regression analysis, the 70 paired measurements of CO from Pivot Breath Sensor and the prescription device produced a line with a slope of 0.9202, a y-intercept of 0.0041 and a correlation coefficient of 0.9710.	*Primary:* Motivation to quit smoking improved in a statistically significant manner, with 38.9% of subjects at day 28 indicating they were thinking of quitting in the next 30 days versus 14.4% at baseline. At 28 days, motivation to quit smoking increased in 29.6%, was unchanged in 66.7%, and decreased in 3.7% of subjects. *Secondary:* By day 28, 28.2% of the intent to treat (ITT) population reported making ≥ 1 quit attempt, and 23.1% reduced their CPD by ≥ 50% compared to baseline.

VII. Substantial Equivalence

The subject *Pivot Breath Sensor* is substantially equivalent to the predicate device, the company's own Carbon Monoxide Breath Sensor System (COBSS) cleared under K171408. Both devices have the same intended use of measuring breath CO levels for single-user over-the-counter ("OTC") use by cigarette smokers (users). The subject device is also similar to the predicate device in fundamental scientific technology. Both are portable, battery powered devices that use electrochemical sensors to non-invasively monitor CO levels. The minor differences in the indications for use statement do not alter the fundamental clinical purpose of the subject device as compared to its predicate, and the minor differences in technological characteristics do not present new questions of safety or effectiveness. Moreover, performance testing demonstrates that the subject device performs as intended and is as safe and effective as the predicate. The table below provides a summary of the similarities and differences between the Pivot Breath Sensor and its predicate device.

Comparison of Subject and Predicate Devices

Characteristic	Subject Device: *Carrot Inc. Pivot Breath Sensor*	Predicate Device: *Carrot Inc. COBSS (K171408)*	Comparison
Intended Use/ Indications for Use	The Pivot Breath Sensor is a breath carbon monoxide monitor intended for single-user use by cigarette smokers as an educational and motivational tool 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 combustible, inhaled products.	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.	Both devices are intended to measure carbon monoxide (CO) in exhaled breath of cigarette smokers. Periodic measurements of CO levels educate users about their smoking exposure and may motivate them to quit smoking.
Environment of Use	Home, office and other Over the counter (OTC) environments		No difference; identical
Design Features	• Non-invasively measures CO in exhaled breath • Hand-held battery powered Visual and audible alarms		No difference; identical
User Interface	Side and Center/Main buttons to activate/ initiate CO breath measurement and to navigate menus.	Main button to activate/initiate CO breath measurement	The side button added has no effect on sensor functionality.
Display	Data (Device settings, CO samples, CO trending) are displayed to the user on the device (sensor) itself via LCD screen.	Data (Device settings, CO samples, CO trending) displayed to user within the *Breath Sensor Application (BSA)* via smartphone.	The location of the display has moved but it still continues to be a digital color display and has no effect on sensor functionality.
Power Source	Rechargeable lithium ion battery		No difference; identical
Sensor Technology	Electrochemical Sensor (1 each CO and H_2 sensor)		No difference; identical

Characteristic	Subject Device: *Carrot Inc. Pivot Breath Sensor*	Predicate Device: *Carrot Inc. COBSS (K171408)*	Comparison
Reported Values	CO levels in parts per million		No difference; identical
Concentration Range	0-100 ppm		No difference; identical
Shelf Life	18 month shelf life	6 month shelf life	Extended shelf-life desired for better user experience.

VIII. Conclusion

The subject and predicate devices have the same intended use and similar indications for use, technological characteristics, and principles of operation. The modifications to the predicate device reflected in the subject device do not alter its fundamental clinical purpose or raise different questions of safety or efficacy, and performance testing supports that the subject device is substantially equivalent to its prior iteration, the *Carbon Monoxide Breath Sensor System (COBSS)*.