510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT

I Background Information:

A 510(k) Number

K201206

B Applicant

Carrot Inc.

C Proprietary and Established Names

Pivot Breath Sensor

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CCJ	Class II	868.1430 Carbon monoxide gas analyzer	Anesthesiology (73)

II Submission/Device Overview:

A Purpose for Submission:

The purpose of this submission is to modify the indications for use for a previously cleared device.

B Measurand:

Carbon Monoxide (CO)

C Type of Test:

Quantitative (Electrochemical Sensor)

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) 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.

C Special Conditions for Use Statement(s):

OTC - Over The Counter

Do not use in cases of suspected carbon monoxide poisoning. Call 911.
Do not use in cases of suspected smoke inhalation (e.g. from a fire). Call 911.
Do not use the Pivot Breath Sensor while it is charging as it will not function.
For use by a single user at home. Do not share your Pivot Breath Sensor with anyone else.

D Special Instrument Requirements:

Pivot Breath Sensor

IV Device/System Characteristics:

A 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. The 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.

B Principle of Operation:

The Pivot Breath Sensor uses electrochemical sensors to quantify the CO level in the breath. These low power electrochemical sensors chemically react with the target gas creating a small current which is measured by device circuitry. The CO Breath Sensor also employs a second electrochemical sensor to detect hydrogen gas and uses this value to adjust the CO sensor measurement for signal due to hydrogen in the breath.

C Instrument Description Information:

1. Instrument Name:

   Pivot Breath Sensor

2. Specimen Identification:

   There is not mechanism to identify the specimen.

3. Specimen Sampling and Handling:

   The user provides a breath sample by exhaling into the device.

4. Calibration:

   The device is calibrated by the manufacturer. There is no option for recalibration by the user.

5. Quality Control:

   External quality controls are not supplied with this device.

V Substantial Equivalence Information:

A Predicate Device Name(s):
Carbon Monoxide Breath Sensor System (COBSS)

B Predicate 510(k) Number(s):
K171408

C Comparison with Predicate(s):

Device & Predicate Device(s):	K201206	K171408
Device Trade Name	Pivot Breath Sensor	Carbon Monoxide Breath Sensor System (COBSS)
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for single-user use by cigarette smokers to inform the user about how breath carbon monoxide levels are affected by smoking behavior	Same
Environment of Use	Over the counter	Same
Design Features	• Non-invasively measures CO in exhaled breath • Hand-held battery powered • Visual and audible alarms • Connects with smartphone through Bluetooth • App for iOS and Android operating systems	Same
Power Source	Rechargeable lithium ion batter	Same
CO Measuring Range	0 – 100 ppm	Same
General Device Characteristic Differences		
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
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.

VI Standards/Guidance Documents Referenced:

Stds No.	Standards Organization	Standards Title	Date
60601-1	IEC	Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance	2005/(R) 2012 and A1:2012, C1:2009/ (R)2012 and A2:2010/(R)2012
60601-1-2	IEC	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests	2014-02
60601-1-6	IEC	Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability	2013-10
60601-1-11	IEC	Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	2010-04
10993-1	ISO	Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process	2009
62366-1	IEC	Medical devices – Part 1: Application of usability engineering to medical devices	2015-02
3A	ISTA	General Simulation Performance Test Procedure Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less	2008

Stds No.	Standards Organization	Standards Title	Date
62304	AAMI / ANSI / IEC	Medical Device Software - Software Life Cycle Processes	2006
14971	ISO	Medical Devices - Application Of Risk Management To Medical Devices	2012

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The sponsor evaluated between-run precision using simulated breath samples collected from eleven devices representing a single manufacturing lot, with three measurements per device for a total of 33 measurements per CO concentration tested. The data was collected by two operators over two days. Results are summarized below:

CO Concentration	0 ppm	5 ppm	10 ppm	20 ppm	50 ppm	100 ppm
n	33	33	33	33	33	33
low	0	4.2	9.1	19.2	48.4	98.7
high	1.3	5	10.2	20.7	51.5	103.6
Mean	0.3	4.5	9.6	19.8	49.9	101.3
SD	0.3	0.2	0.3	0.4	0.8	1.4
CV (%)	90.8	3.9	2.8	1.8	1.7	1.4

The same data were used to calculate repeatability (with-run precision) and the results are summarized below.

Pivot Breath Sensor - Room Temperature						
CO Concentration	**0 ppm**			**Mean**	**SD**	**CV**
Device #1	0.3	0.0	0.1	0.1	0.15	114.56
Device #2	0.4	0.4	0.1	0.3	0.17	57.74
Device # 3	0.1	0.0	0.2	0.1	0.10	100.00
Device # 4	0.0	0.9	0.2	0.4	0.47	128.89
Device # 5	0.3	0.3	0.4	0.3	0.06	17.32
Device # 6	0.1	0.6	1.3	0.7	0.60	90.42
Device # 7	0.4	0.4	0.4	0.4	0.00	0.00
Device # 8	0.0	0.2	0.1	0.1	0.10	100.00
Device # 9	0.0	0.2	0.5	0.2	0.25	107.85

Device # 10	0.4	0.3	0.2	0.3	0.10	33.33
Device # 11	0.4	0.2	0.3	0.3	0.10	33.33

Pivot Breath Sensor - Room Temperature						
CO Concentration	**5 ppm**			**Mean**	**SD**	**CV**
Device #1	4.3	4.7	4.3	4.4	0.23	5.21
Device #2	4.5	4.4	4.4	4.4	0.06	1.30
Device # 3	4.8	4.8	4.8	4.8	0.00	0.00
Device # 4	4.5	4.7	4.6	4.6	0.10	2.17
Device # 5	4.4	4.4	4.2	4.3	0.12	2.66
Device # 6	4.5	4.3	4.4	4.4	0.10	2.27
Device # 7	4.5	5.0	4.7	4.7	0.25	5.32
Device # 8	4.3	4.5	4.5	4.4	0.12	2.60
Device # 9	4.4	4.6	4.6	4.5	0.12	2.55
Device # 10	4.5	4.7	4.5	4.6	0.12	2.53
Device # 11	4.6	4.5	4.5	4.5	0.06	1.27

Pivot Breath Sensor - Room Temperature						
CO Concentration	**10 ppm**			**Mean**	**SD**	**CV**
Device #1	9.7	9.7	9.6	9.7	0.06	0.60
Device #2	9.9	9.4	9.6	9.6	0.25	2.61
Device # 3	10.2	9.9	10.0	10.0	0.15	1.52
Device # 4	9.8	9.9	9.6	9.8	0.15	1.56
Device # 5	9.8	9.5	9.6	9.6	0.15	1.59
Device # 6	9.5	9.4	9.3	9.4	0.10	1.06
Device # 7	10.0	9.9	9.9	9.9	0.06	0.58
Device # 8	9.5	9.3	9.5	9.4	0.12	1.22
Device # 9	9.2	9.4	9.1	9.2	0.15	1.65
Device # 10	9.5	9.7	9.7	9.6	0.12	1.20
Device # 11	9.2	9.4	9.3	9.3	0.10	1.08

Pivot Breath Sensor - Room Temperature						
CO Concentration	**20 ppm**			**Mean**	**SD**	**CV**
Device #1	19.8	20.0	19.7	19.8	0.15	0.77
Device #2	19.9	19.8	19.7	19.8	0.10	0.51
Device # 3	20.3	20.4	20.7	20.5	0.21	1.02
Device # 4	20.1	19.9	20.1	20.0	0.12	0.58
Device # 5	20.0	20.1	19.7	19.9	0.21	1.04
Device # 6	19.4	19.5	19.4	19.4	0.06	0.30
Device # 7	20.2	20.3	20.0	20.2	0.15	0.76
Device # 8	19.8	19.8	19.5	19.7	0.17	0.88
Device # 9	19.2	19.3	19.4	19.3	0.10	0.52
Device # 10	19.9	20.1	20.0	20.0	0.10	0.50
Device # 11	19.2	19.4	19.5	19.4	0.15	0.79

Pivot Breath Sensor - Room Temperature						
CO Concentration	**50 ppm**			**Mean**	**SD**	**CV**
Device #1	49.9	50.2	49.9	50.0	0.17	0.35
Device #2	50.0	50.2	49.9	50.0	0.15	0.31
Device # 3	51.2	51.5	51.2	51.3	0.17	0.34
Device # 4	50.8	50.6	50.7	50.7	0.10	0.20
Device # 5	49.9	50.2	50.1	50.1	0.15	0.31
Device # 6	49.3	49.1	49.3	49.2	0.12	0.23
Device # 7	50.9	50.6	50.7	50.7	0.15	0.30
Device # 8	49.9	49.6	49.5	49.7	0.21	0.42
Device # 9	48.5	48.4	48.6	48.5	0.10	0.21
Device # 10	50.0	50.4	50.7	50.4	0.35	0.70
Device # 11	48.6	48.6	49.3	48.8	0.40	0.83

Pivot Breath Sensor - Room Temperature						
CO Concentration	**100 ppm**			**Mean**	**SD**	**CV**
Device #1	101.8	101.1	101.1	101.3	0.40	0.40
Device #2	101.6	101.2	101.2	101.3	0.23	0.23
Device # 3	103.3	103.4	103.6	103.4	0.15	0.15
Device # 4	102.7	102.0	102.1	102.3	0.38	0.37
Device # 5	101.9	101.3	101.4	101.5	0.32	0.32
Device # 6	100.0	100.0	99.6	99.9	0.23	0.23
Device # 7	102.8	102.7	102.5	102.7	0.15	0.15
Device # 8	101.2	100.6	100.3	100.7	0.46	0.46
Device # 9	98.7	99.0	99.4	99.0	0.35	0.35
Device # 10	102.7	102.9	102.9	102.8	0.12	0.11
Device # 11	99.1	99.2	100.4	99.6	0.72	0.73

The data demonstrate acceptable within run and between run precision.

To evaluate lot-to-lot precision, the sponsor conducted testing on two additional lots of devices for a total of three lots of devices evaluated. Eleven (11) devices from each lot were used to perform 3 breath tests at each CO concentrations tested.

CO Concentration (ppm)	**Mean**	**N**	**Within Lot**		**Between Lot**		**Total Precision**	
			SD	**%CV**	**SD**	**%CV**	**SD**	**%CV**
5	4.5	96	0.29	6.4	0.07	1.6	0.30	6.7
10	9.3	96	0.33	3.5	0.27	2.9	0.43	4.6
20	19.1	96	0.34	1.8	0.52	2.7	0.62	3.2
50	49.1	96	0.67	1.4	0.79	1.6	1.04	2.1
100	98.8	96	1.21	1.2	0.98	1.0	1.56	1.6

The data demonstrate acceptable within lot and between lot precision.

The sponsor performed a study to demonstrate that the device produces precise and accurate results over the claimed temperature range of 40°F - 104°F (4°C - 40°C). For each tested temperature of 5°C, 10°C, 20°C, 30°C, and 40°C, CO concentrations at 5 ppm, 20 ppm, 50 ppm, and 100 ppm were tested on simulated breath samples in three replicates on each of 11 devices. CO concentration of 10 ppm was evaluated at temperature of 4°C, 10°C, 20°C, 30°C, and 40°C in two replicates on each of 11 devices. Results are summarized below:

	Pivot Breath Sensor: 5°C				
CO Concentration	**5 ppm**	**10 ppm**	**20 ppm**	**50 ppm**	**100 ppm**
mean	4.5	9.4	19.4	49.0	98.7
SD	0.3	0.4	0.5	1.0	1.9
CV (%)	6.3	3.7	2.5	2.0	2.0
% recovery	89.5	94.1	97.1	98.0	98.7

	Pivot Breath Sensor: 10°C				
CO Concentration	**5 ppm**	**10 ppm**	**20 ppm**	**50 ppm**	**100 ppm**
mean	4.5	9.5	19.6	49.9	100.4
SD	0.2	0.2	0.4	0.7	1.2
CV (%)	5.4	2.6	2.1	1.3	1.2
% recovery	89.3	94.9	97.9	99.7	100.4

	Pivot Breath Sensor: 20°C				
CO Concentration	**5 ppm**	**10 ppm**	**20 ppm**	**50 ppm**	**100 ppm**
mean	4.7	9.6	19.7	49.0	98.2
SD	0.2	0.4	0.4	1.1	1.7
CV (%)	4.3	3.9	2.2	2.1	1.7
% recovery	93.7	96.5	98.3	98.0	98.2

	Pivot Breath Sensor: 30°C				
CO Concentration	**5 ppm**	**10 ppm**	**20 ppm**	**50 ppm**	**100 ppm**
mean	4.6	9.8	19.8	49.4	98.3
SD	0.3	0.3	0.5	0.9	1.5
CV (%)	5.5	2.6	2.4	1.9	1.5
% recovery	91.5	97.8	99.1	98.8	98.3

	Pivot Breath Sensor: 40°C				
CO Concentration	**5 ppm**	**10 ppm**	**20 ppm**	**50 ppm**	**100 ppm**
mean	4.3	9.2	20.1	50.1	100.4
SD	0.3	0.6	0.6	1.2	2.1
CV (%)	7.3	6.2	2.8	2.3	2.1
% recovery	86.4	92.3	100.4	100.3	100.4

The data demonstrate that the device produces precise and accurate results over the claimed temperature range of 4°C - 40°C.

The sponsor performed a study to demonstrate that the device produces precise and accurate results in 10% and 90% non-condensing humidity. Utilizing an environmental chamber, CO concentrations of 5 ppm, 10 ppm, 20 ppm, 50 ppm, and 100 ppm were tested on simulated breath samples in two replicates on each of 11 devices at each humidity level. Results are summarized below:

	Pivot Breath Sensor: 10% RH				
Concentration	**5 ppm CO**	**10 ppm CO**	**20 ppm CO**	**50 ppm CO**	**100 ppm CO**
mean	4.0	8.7	18.1	47.4	96.2
SD	0.6	0.8	0.6	1.1	1.6
CV (%)	15.6	8.7	3.5	2.2	1.7
% recovery	80.3%	86.5%	90.5%	94.8%	96.2%

	Pivot Breath Sensor: 90% RH				
Concentration	**5 ppm CO**	**10 ppm CO**	**20 ppm CO**	**50 ppm CO**	**100 ppm CO**
mean	4.2	9.0	18.4	47.5	96.9
SD	0.4	0.6	0.5	0.8	1.3
CV (%)	9.5	7.0	2.8	1.7	1.3
% recovery	83.5%	90.3%	91.9%	95.0%	96.9%

The data demonstrate that the device produces precise and accurate results at 10-90% non-condensing humidity.

2. Linearity:

The sponsor evaluated linearity through a recovery study. Simulated breath samples at 0 ppm, 5 ppm, 10 ppm, 20 ppm, 50 ppm, and 100 ppm CO were prepared and analyzed in replicates of 3, on each of 11 devices, for a total of 33 replicates per concentration. The summary of the linear regression analysis of the data comparing the measured results with the target concentrations is presented below:

Slope	**Intercept**	**r^2**	**Range tested**	**Claimed Range**
1.013	-0.3809	0.9995	0-100.2	0 – 100 ppm

Average percent recoveries for the non-zero concentrations were determined, as follows:

Concentration	Average Recovery (%)
5	90.91
10	85.58
20	98.03
50	99.88
100	101.12

The linearity studies support the sponsor's claimed measuring range as described in the table above.

3. Analytical Specificity/Interference:

The sponsor evaluated the potential for interference from gases other than CO that could be present in exhaled breath by comparing the results from samples containing CO at 20 ppm to samples containing CO at 20 ppm plus one of the potential interferents listed below at 23°C. The sponsor determined that compounds that affected the device results by more than 5 ppm were considered to be cross-sensitive. The mean of the control group (no interfering gases) was 18.3 ppm. The potential interfering gas, the concentration tested, and the mean difference observed are summarized in the table below.

Potential Interferent	Concentration Tested (ppm)	Mean Difference Observed (ppm)
Hydrogen Sulfide	15	0.4
Sulfur Dioxide	5	0.2
Nitrogen Dioxide	5	0.5
Nitric Oxide	35	8.4
Ethylene	100	11.4
Ethanol	200	0.2

4. Assay Reportable Range:

The claimed measuring range is 0 -100 ppm.

5. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

There are no calibrators or external controls included with the device. Calibration is performed with two gases of known concentration (50 ppm CO and 100 ppm H_2) at the factory. There is no option for recalibration. Product composition is verified by direct comparison to the calibrated standards. Primary Standard Gas Mixtures are traceable to National Institute of Standards and Technology (NIST) weights and/or NIST Gas Mixture reference materials.

6. Detection Limit:

   Not applicable.

7. Assay Cut-Off:

   Not applicable.

8. Accuracy:

   The sponsor performed an accuracy study comparing the CO results from 70 lay user study participants. All of the participants self-reported smoking 2 or more cigarettes per day. There were 40 male and 30 female study participants, with 34 participants in the 18-49-year-old age range and 36 participants in the 50-80-year-old age range.

   Participants self-tested breath samples on the candidate device (Pivot Breath Sensor) and then provided a breath sample at the direction of a health care professional to test using the comparator method (Micro Smokerlyzer). Each participant self-tested using a unique candidate device (i.e. devices were not shared between participants). Three Micro Smokerlyzer from three different lots were rotated over the course of the study.

   Seventy paired CO measurements from the candidate and the comparator device were obtained. Concentrations for the comparator device ranged from 2 to 61 ppm. A regression model was fit using the 70 paired CO measurements from the candidate and the predicate devices that produced a line equation with a slope of 0.9202, a y-intercept of 0.0041 and a correlation coefficient of 0.9710.

9. Carry-Over:

   The device monitors the gas sensor signals to determine when the gas has cleared from the device sufficiently to allow for another sample to be taken. If the user attempts to start a new sample before this clearing has occurred, the sensor will not allow the user to give a sample but will state that the sensor is clearing and to try again after a short wait. The sensor is typically able to clear and prepare for a new sample within about 1 minute after a breath is given, however if the breath has a higher concentration of hydrogen, up to 3 minutes.

B Comparison Studies:

1. Method Comparison with Predicate Device:

   See section VII.A.8. Accuracy.

2. Matrix Comparison:

   Not applicable. This test is only for breath samples.

C Clinical Studies:

1. Clinical Sensitivity:

   Not applicable.

2. Clinical Specificity:

   Not applicable.

3. Other Clinical Supportive Data (When 1. and 2. Are Not Applicable):

   As part of the sponsor's analytical performance study comparing the performance of the Pivot Breath Sensor to the Micro^{+} Smokerlyzer, the sponsor evaluated the usability of the device and labeling. For the results of the comparison to the comparator device, please refer to section VII.A.8. above. The mean number of cigarettes smoked per day reported by the participants was 13.8 (± 7.3) cigarettes/day with a range of 2 to 30 cigarettes/day.
   The results of the usability and labeling comprehension study are reviewed below.

   Self-Training
   Study participants self-trained on the candidate device (Pivot Breath Sensor) using the device labeling, which included the product packaging and Quick Start Guide (QSG).

   The self-training by the materials provided in the labeling included the submission of one (1) Guided Breath Test (GBT) using the candidate device as described in the User Manual. Results from this first test were as follows:

   Table 1. User interpretation of user's own results

Participant CO Category	**Correct/Total (% Correct)**
Green	13/15 (87%)
Orange	7/7 (100%)
Red	48/48 (100%)

   Performance Breath Test

   The participant then provided a second breath sample that was used as the performance breath sample and was asked to interpret the result.

   Table 2. User interpretation of user's own results during performance breath test

Participant CO Category	**Correct/Total (% Correct)**
Green	13/14 (93%)
Orange	6/6 (100%)
Red	49/50 (98%)

D Clinical Cut-Off:

Not applicable.

E Expected Values/Reference Range:

The following ranges were established from literature:

0 – 6 ppm: Typical level for non-smokers or smokers who have not smoked for an extended period of time.

7 – 9 ppm: Borderline values that may be found in smokers and non-smokers.

10+ ppm: Typical levels for a smoker.

F Other Supportive Instrument Performance Characteristics Data:

Not applicable.

VIII Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Parts 801 and 809, as applicable.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.