510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:

k171408

B. Purpose for Submission:

New device

C. Manufacturer and Instrument Name:

Carrot Sense, Inc. Carbon Monoxide Breath Sensor System (COBSS)

D. Type of Test or Tests Performed:

Quantitative (electrochemical sensor)

E. System Descriptions:

1. Device Description:

   The Carbon Monoxide Breath Sensor System (COBSS) is a breath carbon monoxide (CO) monitor for single person use. The COBSS is a portable, battery-powered device that is composed of the following:

   - A hand-held CO breath sensor that uses electrochemical technology to sample the gas from a user's exhaled breath, and a microprocessor to convert the output from the sensor to a CO concentration.
   - A mobile phone (smartphone) software application (the Breath Sensor Application (BSA)) which displays the exhaled breath CO value to the user.

   The Carbon Monoxide Breath Sensor System (COBSS) pairs to the BSA on the smartphone via low-energy Bluetooth. The most recent exhaled breath CO value is displayed at the top of the smartphone screen with several visual characteristics for user interpretation: results are displayed in parts-per-million ("ppm"), and as a color color coded bar that is related to the ppm value: green (0 – 6 ppm CO), orange (7 – 9 ppm CO), or red (≥ 10 ppm CO). The graphical display shows the user their relative levels of exhaled breath CO throughout the day and between days.

2. Principle of Operation:

   The Carbon Monoxide Breath Sensor System (COBSS) uses electrochemical sensors to quantify the CO level in the breath. The sensor chemically reacts with CO, 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.

3. Modes of Operation:

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes ☑ or No ☐

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes ☑ or No ☐

4. Specimen Identification:

   There is no mechanism to identify the specimen.

5. Specimen Sampling and Handling:

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

6. Calibration:

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

7. Quality Control:

   External quality controls are not supplied with this device.

8. Software:

   FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

   Yes ☑ or No ☐

F. Regulatory Information:

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

G. Intended Use:

1. Indication(s) 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.

2. Special Conditions for Use Statement(s):

   For over the counter use.
   Not for multiple person use.
   Not for use in cases of suspected carbon monoxide poisoning.
   Not for use in cases of suspected fire smoke inhalation.
   Not for point of care use in clinical settings.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

   Bedfont Scientific LTD. Micro+ Smokerlyzer (k082315)

2. Comparison with Predicate Device:

Similarities

Feature	Subject Device: Carrot Sense COBSS	Predicate Device: Bedfont Scientific 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 COBSS	Predicate Device: Bedfont Scientific Micro+ Smokerlyzer (k082315)
Environment of Use	Over the counter	Prescription use only
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	• 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

I. Special Control/Guidance Document Referenced (if applicable):

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	2008

Stds No.	Standards Organization	Standards Title	Date
		kg (150 lb) or Less	
62304	AAMI / ANSI / IEC	Medical Device Software - Software Life Cycle Processes	2006
14971	ISO	Medical Devices - Application Of Risk Management To Medical Devices	2012

J. Performance Characteristics:

1. Analytical Performance:

a. Accuracy:

The sponsor performed an accuracy study comparing the CO results from 70 lay user study participants who provided breath samples on both the predicate and candidate devices. All of the participants self-reported smoking 2 or more cigarettes per day. There were 38 male and 32 female study participants, with 39 participants in the 18-49 year old age range and 31 participants in the 50-80 year old age range.

Seventy paired CO measurements from the candidate and the predicate device were obtained, and concentrations for the predicate device ranged from 2 to 66 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 0.9289, a y-intercept of -0.0306 and a correlation coefficient of 0.9878.

Accuracy of the candidate device was also assessed by comparing the concordance between the color categories obtained from the candidate device and the predicate device, and the results are summarized in the following tables.

Predicate: 19 Green results			
	Green	Orange	Red
Candidate	18	1	0

The discordant candidate result was 7 ppm.

Predicate: 7 Orange results			
	Green	Orange	Red
Candidate	2	5	0

The discordant candidate results were 4 and 6 ppm.

Predicate: 44 Red results			
	Green	Orange	Red
Candidate	0	3	41

The discordant candidate results were 8, 8, and 9 ppm.

Accuracy within the claimed acceptable temperature range for use was also determined: see section J.1.b

b. Precision/Reproducibility:

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

CO Concentration	**0 ppm**	**5 ppm**	**10 ppm**	**20 ppm**	**50 ppm**	**100 ppm**
mean	0.5	5.8	10.8	19.8	47.9	99.0
SD	0.4	0.8	0.9	1.1	2.2	5.3
CV(%)	76.7	13.8	8.8	5.6	4.6	5.4
low	0	4.7	9.5	17.5	42.7	89.3
high	1.4	8.3	14.2	22.4	51.6	109.2
n	33	33	33	33	33	33

The same data was used to calculate repeatability (within-run precision) and the results are summarized below:

CO Concentration	**0 ppm**			mean	SD	CV
Device #1	0.6	0.4	0.4	0.5	0.1	24.7
Device #2	0.3	0.5	0.5	0.4	0.1	26.6
Device # 3	0.4	0.9	1.1	0.8	0.4	45.1
Device # 4	1.2	1.2	1.3	1.2	0.1	4.7
Device # 5	0	0.2	0.8	0.3	0.4	124.9
Device # 6	0.6	0.3	1.2	0.7	0.5	65.5
Device # 7	0.8	0.5	0.5	0.6	0.2	28.9
Device # 8	0	0	0	0.0	0.0	0.0
Device # 9	0.3	0.4	0.4	0.4	0.1	15.7
Device # 10	0.2	1.4	1	0.9	0.6	70.5
Device # 11	0.1	0.1	0.3	0.2	0.1	69.3

CO Concentration	5 ppm			mean	SD	CV
Device #1	5.6	4.9	5.3	5.3	0.4	6.7
Device #2	5.3	5.1	5.9	5.4	0.4	7.7
Device # 3	7.2	5.8	8.3	7.1	1.3	17.6
Device # 4	6.5	6.4	5.5	6.1	0.6	9.0
Device # 5	5.3	5.1	5.3	5.2	0.1	2.2
Device # 6	5.3	5.7	5.6	5.5	0.2	3.8
Device # 7	5.2	6.1	6.6	6.0	0.7	11.9
Device # 8	4.9	4.8	6.7	5.5	1.1	19.6
Device # 9	6.2	6.3	7	6.5	0.4	6.7
Device # 10	5.2	6.5	5.7	5.8	0.7	11.3
Device # 11	6.4	4.7	5.3	5.5	0.9	15.8

CO Concentration	10 ppm			mean	SD	CV
Device #1	10.1	10.3	9.9	10.1	0.2	2.0
Device #2	9.6	10.1	10.4	10.0	0.4	4.0
Device # 3	14.2	11.9	11.1	12.4	1.6	13.0
Device # 4	10.9	11.2	10.5	10.9	0.4	3.2
Device # 5	11.1	11.1	11.4	11.2	0.2	1.5
Device # 6	9.5	10.3	10.3	10.0	0.5	4.6
Device # 7	11.4	9.9	10.5	10.6	0.8	7.1
Device # 8	10.4	10.3	9.6	10.1	0.4	4.3
Device # 9	11	11.9	12.9	11.9	1.0	8.0
Device # 10	10.6	10.8	10.7	10.7	0.1	0.9
Device # 11	10.3	10.4	10.5	10.4	0.1	1.0

CO Concentration	20 ppm			mean	SD	CV
Device #1	19.8	19.3	18.2	19.1	0.8	4.3
Device #2	19.2	18.9	20.2	19.4	0.7	3.5
Device # 3	20.9	21	20.4	20.8	0.3	1.5
Device # 4	19.8	20.4	19.3	19.8	0.6	2.8
Device # 5	21.3	20.9	19.7	20.6	0.8	4.0
Device # 6	18.9	17.5	18.5	18.3	0.7	3.9
Device # 7	18.9	20.3	21.7	20.3	1.4	6.9
Device # 8	19.1	18.3	18.8	18.7	0.4	2.2
Device # 9	19.1	22.4	21.6	21.0	1.7	8.2
Device # 10	19.9	20.3	19.3	19.8	0.5	2.5
Device # 11	20.3	19.9	20.1	20.1	0.2	1.0

CO Concentration	50 ppm			mean	SD	CV
Device #1	44.7	46.3	45.7	45.6	0.8	1.8
Device #2	48.6	48.6	48.7	48.6	0.1	0.1
Device # 3	47.3	49.7	49.3	48.8	1.3	2.6
Device # 4	46.8	47.9	46.8	47.2	0.6	1.3
Device # 5	51	50.9	51.6	51.2	0.4	0.7
Device # 6	45.7	43.6	42.7	44.0	1.5	3.5
Device # 7	49.8	49.9	48.4	49.4	0.8	1.7
Device # 8	47.4	47.7	45.4	46.8	1.3	2.7
Device # 9	51	49.9	49.6	50.2	0.7	1.5
Device # 10	47.5	46.2	44.9	46.2	1.3	2.8
Device # 11	49.2	49.2	49.5	49.3	0.2	0.4

CO Concentration	100 ppm			mean	SD	CV
Device #1	92.4	93.6	93.2	93.1	0.6	0.7
Device #2	103.6	99.9	101.1	101.5	1.9	1.9
Device # 3	100.8	99.7	99.7	100.1	0.6	0.6
Device # 4	98.2	96.8	96.6	97.2	0.9	0.9
Device # 5	106.7	106.6	105.8	106.4	0.5	0.5
Device # 6	90.6	89.3	89.3	89.7	0.8	0.8
Device # 7	99.2	99.4	97.5	98.7	1.0	1.1
Device # 8	97.6	95	96.2	96.3	1.3	1.4
Device # 9	109.2	108.8	104	107.3	2.9	2.7
Device # 10	96.1	97.3	94.1	95.8	1.6	1.7
Device # 11	104.4	102.1	102.1	102.9	1.3	1.3

The sponsor also 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, 10 ppm, 20 ppm, 50 ppm, and 100 ppm were tested on simulated breath samples in duplicate on each of eleven devices. Results are summarized below:

5° C

CO Concentration	5 ppm	10 ppm	20 ppm	50 ppm	100 ppm
mean	4.4	9.2	18.4	47.1	98.9
SD	0.5	1.1	1.5	3.2	6.5
CV(%)	11.2	12.2	8.3	6.7	6.6
% recovery	88.0	92.0	92.0	94.2	98.9

10° C

CO Concentration	5 ppm	10 ppm	20 ppm	50 ppm	100 ppm
mean	4.8	9.5	19.0	47.6	98.6
SD	0.5	0.8	1.3	3.0	6.7
CV(%)	10.2	8.6	6.7	6.3	6.8
% recovery	96.0	95.0	95.0	95.2	98.6

20° C

CO Concentration	5 ppm	10 ppm	20 ppm	50 ppm	100 ppm
mean	4.7	9.2	18.9	48.1	98.8
SD	0.5	0.7	1.2	2.5	6.0
CV(%)	9.8	7.6	6.3	5.2	6.0
% recovery	94.0	92.0	94.5	96.2	98.8

30° C

CO Concentration	5 ppm	10 ppm	20 ppm	50 ppm	100 ppm
mean	4.8	9.8	19.0	49.3	101.9
SD	0.7	0.7	1.1	2.6	5.7
CV(%)	15.2	7.2	5.8	5.3	5.6
% recovery	96.0	98.0	95.0	98.6	101.9

40° C

CO Concentration	5 ppm	10 ppm	20 ppm	50 ppm	100 ppm
mean	4.4	9.2	18.6	50.1	104.0
SD	0.5	0.5	1.1	3.1	5.6
CV(%)	11.8	5.5	6.1	6.2	5.4
% recovery	88.0	92.0	93.0	100.2	104.0

c. *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 an total of 33 replicates per concentration. A linear regression analysis comparing the measured results with the target concentrations produced the following line equation:

$Y = 0.978x + 0.487$ $R^2 = 0.995$

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

Concentration	Aveage recovery (%)
5	116.2
10	107.6
20	99.1
50	95.8
100	99.0

d. Carryover:

The device contains a lockout feature which prevents the the user from performing a breath test if a breath test has been performed or attempted in the previous 5 minutes.

e. Interfering Substances:

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 containg CO at 20 ppm plus one of the potential interferents listed below. The potential interfering gas, the concentration tested, and the mean difference observed are summarized in the table below.

Potential Interferent	Concentration Tested	Mean Difference Observed
Hydrogen Sulfide	15 ppm	0.2 ppm
Sulfur Dioxide	5 ppm	0.2 ppm
Nitrogen Dioxide	5 ppm	0.1 ppm
Nitric Oxide	35 ppm	1.3 ppm
Ethylene	100 ppm	-1.1 ppm
Ethanol	200 ppm	0.3 ppm

2. Other Supportive Instrument Performance Data Not Covered Above:

Lay user labeling comprehension: Seventy lay users were instructed to read the proposed device instructions for use, and to rate how well they understood the instructions, and to rate the ease of use of the device. The lay users were also asked to interpret the device results. Lay users in the study found the device easy to use, and users understood that device results do not indicate that it is safe to smoke.

K. Proposed Labeling:

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

L. Conclusion:

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