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

I Background Information:

A 510(k) Number

K211918

B Applicant

Bedfont Scientific Ltd

C Proprietary and Established Names

iCOquit® Smokerlyzer®

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
CCJ	Class II	21 CFR 868.1430 - Carbon Monoxide Gas Analyzer	Anesthesiology (73)

II Submission/Device Overview:

A Purpose for Submission:

New 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 iCOquit® Smokelyzer® breath carbon monoxide (CO) monitor is intended for single patient use by cigarette smoking individuals, notifying the individual user of the amount of CO on their breath produced as a consequence of smoking activity. The device can be used in smoking cessation programmes.

C Special Conditions for Use Statement(s):

OTC – Over-the-Counter

D Special Instrument Requirements:

This device is for individual use only.
Not for use with other inhaled products.
For indoor use only.
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.

IV Device/System Characteristics:

A Device Description:

The subject device is a handheld exhaled breath monitor for the detection of carbon monoxide (CO) on the breath. The subject device is a personal stop-smoking device that works in conjunction with the iCOquit® app developed for smartphone or tablet, which the user pairs to the device via Bluetooth. It is powered by a non-rechargeable 3v lithium-ion coin cell battery.

<u>The iCOquit® Smokerlyzer® consists of the following components:</u>
• iCOquit® Smokerlyzer®: Device with breath sample port, on/pairing button, LED light
• ring/pairing light, breath exhaust
• iCOquit® app: Smartphone or Tablet Application
• One-piece handheld breath CO monitor

B Principle of Operation:

The iCOquit® Smokerlyzer® detects CO on breath using an electrochemical sensor. The sensor reacts to the presence of CO in the breath sample provided, producing an electrical output. The output is then amplified into a meaningful result by the device. The result is sent to the iCOquit® App.

C Instrument Description Information:

1. Instrument Name:

   iCOquit® Smokelyzer®

2. Specimen Identification:

   There is not mechanism to identify the specimen.

3. Specimen Sampling and Handling:

   User exhalation through integrated breath port

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):	K211918	K171408
Device Trade Name	iCOquit® Smokerlyzer®	Carbon Monoxide Breath Sensor System (COBSS)
General Device Characteristic Similarities		
Intended Use/Indications For Use	Intended for single-patient use by cigarette smokers in smoking cessation programs to inform the user about how breath carbon monoxide levels are affected by smoking behavior	Same

Device & Predicate Device(s):	K211918	K171408
Measurement Range	0 – 100 PPM (parts per million)	Same
General Device Characteristic Differences		
Sensor Life	500 breath tests/12 months. Whichever occurs first	18 months
Battery Info	Lithium battery (Lithium-ion coin cell) 12 months lifespan (non-rechargeable)	Lithium Battery – Lifespan: 7 day per charge.
Operating Temperature	59°-95° Fahrenheit (15°-35° Celsius)	40°-104° Fahrenheit (4°- 40° Celsius)
Breath Hold	15 seconds	10 seconds

I Standards/Guidance Documents Referenced:

Standards Designation Number and Date	Title
ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
60601-1-11 Edition 2.0 2015-01	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
60601-1-2 Edition 4.0 2014-02	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
10993-1 Fifth Edition 2018-08	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
14971 Third Edition 2019-12	Medical Devices – Application of risk management to medical devices
62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software – software life cycle process

Standards Designation Number and Date	Title
62366-1 Edition 1.0 2015- 02	Medical devices – Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]
15223-1 Third Edition 2016-11-01	Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied – Part 1: General requirements

Guidance Document	Issue Date
Design Considerations for Devices Intended for Home Use	November 2014
Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions (510(k)s) for Reprocessed Single-Use Medical Devices	June 2004
Use of International Standard ISO10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"	September 2020
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	May 2005
Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices	July 2016
Radio Frequency Wireless Technology in Medical Devices	August 2013
Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions	December 2019

VI Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

The sponsor evaluated between-run precision using simulated breath samples tested using three devices, with ten measurements per device for a total of 30 measurements per CO concentration tested. The results are summarized below:

CO concentration	0 ppm	21 ppm	51 ppm	102 ppm
Mean	0.4	20.8	50.3	103.7
SD	0.6	1.4	2.7	3.2
CV %	155.4	6.7	5.3	3.1
Low	0	18	47	97
High	2	23	55	111
N#	30	30	30	30

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

Expected CO concentration 0 ppm	Mean ppm	SD	CV
Device 1	0.4	0.7	174.8
Device 2	0.4	0.5	129.1
Device 3	0.4	0.7	174.8

Expected CO concentration 21 ppm	Mean ppm	SD	CV
Device 1	21.1	1.0	4.7
Device 2	21.5	1.2	5.5
Device 3	19.8	1.5	7.5

Expected CO concentration 51 ppm	Mean ppm	SD	CV
Device 1	49.7	2.3	4.7
Device 2	51.4	3.1	6.0
Device 3	49.8	2.4	4.9

Expected CO concentration 102 ppm	Mean ppm	SD	CV
Device 1	102.7	1.7	1.7
Device 2	106.4	1.8	1.7
Device 3	102	3.7	3.6

The sponsor also performed a study to demonstrate that the device produces precise and accurate results over the claimed temperature range of 15°C - 35°C. For each tested temperature of 15°C, 25°C & 35°C, CO concentrations at 0ppm, 5ppm, 10ppm, 20ppm, 50ppm, and 100ppm were tested on simulated breath samples on each of three devices with 3 replicates and 6 test per device (n=18).
Results are summarized below:

15˚C

CO Concentration	0 ppm	5 ppm	10 ppm	20 ppm	50 ppm	100 ppm
Mean	0.4	4.7	10.1	21.9	50.6	98.1
SD	0.6	0.8	1.1	0.8	1.3	1.4
CV%	150.0	17.0	10.9	3.7	2.6	1.5

25˚C

CO Concentration	0 ppm	5 ppm	10 ppm	20 ppm	50 ppm	100 ppm
Mean	0.6	4.9	10.6	21.1	51.0	100.9
SD	0.7	0.7	1.0	0.8	0.7	1.4
CV%	116.7	14.3	9.4	3.8	1.4	1.4

35˚C

CO Concentration	0 ppm	5 ppm	10 ppm	20 ppm	50 ppm	100 ppm
Mean	0.9	4.9	10.4	20.8	51.1	99.9
SD	0.7	0.9	1.3	0.5	1.4	2.6
CV%	77.8	18.4	12.5	2.4	2.8	2.6

2. Linearity:

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 3 devices, for a total of 9 replicates per concentration. A linear regression analysis comparing the measured results with the target concentrations produced the following line equation:

$y = 1.0236x - 0.3211$ $R^2 = 0.9981$

The linearity studies support the sponsor's claimed measuring range of 0 to 100 ppm.

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. 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 (ppm)**
Oxygen	99.999%	0.6
Carbon Dioxide	5.05%	-0.1
Nitric oxide	210ppb	0.8
Ethanol	1000ppm	0.2
Ammonia	100ppm	1.3
Acetone	100ppm	0.2
Hydrogen Sulfide	5ppm	-0.7
Acetonitrile	500ppm	0.0
Acetaldehyde	1000ppm	-0.1
Isoprene	1000ppm	-0.7
Hydrogen	50ppm	0.8

4. Accuracy (Instrument):

Fifty-four paired CO measurements from the candidate iCOquit® Smokerlyzer® and the Bedfont Scientific Micro+™ Smokerlyzer device were obtained, and concentrations for the Micro+™ device ranged from 0 to 99 ppm. A regression model was fit using the 54 paired CO measurements from the candidate and the Micro+™ devices that produced a line equation with a slope of 0.9732, y-intercept of 0.9847 and a correlation coefficient of 0.9978.

5. Carry-Over:

Not applicable. Carryover could be observed in devices that are intended for multiple patient use where a non-smoker takes a test within quick succession of a heavy smoker. The candidate device is intended for a single person use, thus taking breath tests within quick succession as their breath CO will not lower substantially due to the half-life of CO being approximately 5 hours.

B Other Supportive Instrument Performance Characteristics Data:

The iCOquit® Smokerlyzer® is for over-the-counter use, in the home use and can also be used in smoking cessation programmes. Testing based upon the FDA guidance document "Applying Human Factors and Usability Engineering to Medical Devices (February 3, 2016)" was performed to ensure safety and effectiveness of the device within the intended use environment in consideration. All participants were able to perform critical tasks which were necessary for the successful use of the iCOquit® Smokerlyzer® device.

VII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

VIII Conclusion:

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