December 21, 2021

Bedfont Scientific Ltd
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K211918
Trade/Device Name: iCOquit® Smokerlyzer®
Regulation Number: 21 CFR 868.1430
Regulation Name: Carbon monoxide gas analyzer
Regulatory Class: Class II
Product Code: CCJ
Dated: October 7, 2021
Received: October 8, 2021

Dear Prithul Bom:

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)*
K211918

Device Name
iCOquit® Smokerlyzer®

Indications for Use *(Describe)*
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.

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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510(K) Number__K211918___

510(k) Summary

This summary of 510(k) information is being submitted in accordance with the requirement of 21 CFR 807.92.

I. SUBMITTER

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Email: louise@bedfont.com
Date of Summary: 13 May 2021

II. SUBJECT DEVICE

Device Name:	iCOquit® Smokerlyzer®
Classification Name:	Analyzer, Gas, Carbon-monoxide, Gaseous-phase
Regulation Description:	Carbon monoxide gas analyzer
Product Regulatory Class:	II
Product Regulatory Code:	CCJ
Review Panel:	Anesthesiology
Code of Federal Regulation:	21 CFR 868.1430

III. PREDICATE DEVICE

Manufacturer:	Carrot Sense Inc
Device Trade Name:	Carbon Monoxide Breath Sensor System (COBSS)
Device 510(k):	K171408
Regulation Description:	Carbon monoxide gas analyzer
Product Regulatory Class:	II
Product Regulatory Code:	CCJ
Code of Federal Regulation:	21 CFR 868.1430

IV. DEVICE DESCRIPTION

The iCOquit® Smokerlyzer® device is a hand-held exhaled breath monitor for the detection of Carbon Monoxide (CO) on the breath, using a non-invasive method of breath analysis to detect levels of Carbon Monoxide (CO).

The iCOquit® Smokerlyzer® device works in conjunction with the iCOquit® App developed for smartphone or tablet, which the user pairs to the device via Bluetooth.

The iCOquit® App works in conjunction with the iCOquit® Smokerlyzer® personal stop-smoking tool to provide visual motivation to help the user quit as well as track their quitting progress in real-time.

The iCOquit® Smokerlyzer® is an over-the-counter, hand-held exhaled breath monitor. It is not for use with other inhaled products. The use of exhaled CO measurements for the rapid estimation of carboxyhaemoglobin levels has been supported as an aid for smoking cessation and a breath CO monitor can be used as a motivational and educational tool in the home environment, including as part of smoking cessation programmes.

Using an electrochemical sensor designed to react specifically to carbon monoxide producing an electrical output, the sensor measures the level of carbon monoxide (CO) on the breath. The output is then amplified into a meaningful result by the device. The result is sent to the iCOquit® App wirelessly, allowing the meaningful result to be displayed on the user's smartphone or tablet.

The App displays the reading received from the iCOquit® Smokerlyzer® on the smartphone or tablet paired with the device and based on the questions the user answers within the App relating to their smoking habits and the CO reading, they will then receive a result from the Fagerstrom Test of Nicotine Dependence.

The sample method for the iCOquit® Smokerlyzer® channels the breath sample exhaled by the user into an integrated breath port on the device. This passes directly over the sensor during the test, ensuring the sensor is exposed to the gas sample for the required length of time to give an accurate reading.

The user is required to hold their breath for a 15 second countdown. This is displayed via the iCOquit® App and guides the user through the process of providing a breath sample for measurement. At the end of the breath hold, the patient shall blow gently but fully into the iCOquit, exhaling as much of the breath in their lungs as possible. The reading shown on the App is the peak reading.

Once a breath test has been completed the user will be navigated to a screen where they will see their CO result in PPM (parts per million) and %COHb (Carboxyhemoglobin). The reading shown on the App is the peak reading. Users are then asked Fagerstrom questions to determine their smoking status of either low, moderate or high and the result is then saved in a graph.

The level of CO measured in PPM is also calculated as %COHB and displayed in the App. The formulas for calculating PPM as %COHb are:

- ≤91ppm: %COHb = 0.63 + 0.16 (PPM)
- >91ppm: %COHb = 15.75 / (80/CO ppm + 0.1575)

V. INTENDED USE / INDICATIONS FOR USE

The iCOquit® Smokerlyzer® 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.

VI. COMPARISON OF TECHNOLGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Table 1 - Table of Similarities and Differences between Predicate and Proposed Device

	Proposed: **Bedfont Scientific Ltd** **iCOquit Smokerlyzer**	**Predicate:** **Carrot Sense** **Carbon Monoxide Breath Sensor System (COBSS)**
510(k)		K171408
Classification Product Code	CCJ – Carbon monoxide gas analyser	CCJ – Carbon monoxide gas analyser
Regulation Number	CFR – 868.1430	CFR – 868.1430
Device Class	Class 2	Class 2
Indications for Use	The iCOquit Smokerlyzer 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.	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 behaviour. The device is not intended to be used with other inhaled products.

Design Features	• Non-invasively measures CO in exhaled breath • Handheld battery powered • Connects with Smartphone or Tablet through Bluetooth • App for iOS and Android operating systems	• Non-invasively measures CO in exhaled breath • Handheld battery powered • Visual and audible alarms • Connects with smartphone through Bluetooth • App for iOS and Android operating systems
Measurement Range	0 – 100 PPM (parts per million)	0 – 100 PPM (parts per million)
Accuracy	±≤3PPM / ±≤10% of reading* *whichever is greater	±20% or 3PPM, whichever is greater
H2 Cross Sensitivity	≤6%	<6%
Power Source	Lithium battery (Lithium-ion coin cell)	Lithium battery
Battery Life	12 months	7 days per charge
Operating Temperature	15°-35° Celsius (59°-95° Fahrenheit)	40°-104° Fahrenheit (4°- 40° Celsius)
Operating Humidity range	10-90% RH non-condensing	10-90% non-condensing
Type of Use	Over the counter	Over the counter
Sensor Technology	Electrochemical Sensor	Electrochemical Sensor
Sensor Life	500 breath tests/12 months. Whichever occurs first	18 months
Sensor Drift	Not Applicable	<5% per annum
Connectivity	Bluetooth	Bluetooth
Breath Hold	15 seconds	10 seconds
Analysis Time	<30 seconds	A few seconds
Interfering gas testing	Yes	Yes
Patient interface	Breath Port Mouthpiece	Detachable Mouthpiece
Contraindications	None	None
Performance	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11
Ingress Protection	IXP0	IP22
Screen	Smartphone/Tablet screen	Small integrated TFT/digital Screen

Our family, innovating health, for yours.

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Registered in: England and Wales. Registered No: 1289798 Issue 3 - February 2017, Part No: MKT361

The iCOquit® Smokerlyzer® Carbon Monoxide Monitor and the Predicate Device are the same for the following reasons:

Technology

The technological principle of the iCOquit® Smokerlyzer® Carbon Monoxide Monitor and the Predicate Device cleared under K171408 is monitoring of Carbon Monoxide (CO) on the breath. They have the following same technologically characteristics:

- An Electrochemical Sensor to detect the level of Carbon Monoxide (CO) on breath
- A non-replaceable Lithium battery power source
- Bluetooth connectivity for pairing the device with a Smartphone or Tablet Application
- Handheld Monitor
- Non-invasive breath sample method
- CO level on breath measured in PPM (Parts Per Million)

Materials

The iCOquit® Smokerlyzer® Carbon Monoxide Monitor and the Predicate Device cleared under K171408 are manufactured from plastic material that has been subject to evaluation in accordance with standard ISO 10993-1 ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.

Indications for Use

Device Name: iCOquit® Smokerlyzer®
Indications for Use: The iCOquit 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 programs.

Predicate Device Name: Carbon Monoxide Breath Sensor System
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.

The iCOquit® Smokerlyzer® 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 programs.

These indications are the same as the Predicate Device cleared under K171408. The Subject and Predicate device are breath carbon monoxide monitors, for single patient use by cigarette smokers. The devices offer a non-invasive method to determine and inform the user of the level of Carbon Monoxide (CO) on their breath produced as a consequence of smoking activity.

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Environment of Use
The iCOquit® Smokerlyzer® Carbon Monoxide Monitor and the Predicate Device cleared under K171408 are both Over-the-Counter devices, which can be used in Smoking Cessation programs.

Labelling
The iCOquit® Smokerlyzer® Carbon Monoxide Monitor and the Predicate Device cleared under K171408 are indicated for Over-the-Counter use and both devices include clear labelling enabling the user to understand their CO Measurement and identify appropriate warnings for safe and effective use.

Labelling of the iCOquit® Smokerlyzer® Carbon Monoxide Monitor is in compliance with the requirements of 21 CFR Part 801, as applicable.

VII. PERFORMANCE DATA

The following performance data was provided in support of the 510(k) application:

Biocompatibility
The materials used in iCOquit® Smokerlyzer® Carbon Monoxide Monitor have been subject to evaluation in accordance with recognized consensus standard ISO 10993-1: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process and are considered safe. After an evaluation of endpoints for consideration, the type of contact for consideration is:

- Surface device, Intact Skin, Limited duration

A typical test with the iCOquit® Smokerlyzer® monitor is <1 minute (between 10-30 seconds). The monitor allows no more than 500 tests maximum to be performed. The predicate device(s) have been considered as also having limited duration of contact. The user only exhales through the device. After an evaluation of endpoints for consideration and the type of contact, end point testing was selected and the following tests were performed:

- Cytotoxicity
- Sensitization
- Irritation

Electrical Safety, EMC, EMI Testing
The iCOquit® Smokerlyzer® Carbon Monoxide Monitor and the Predicate Device cleared under K171408 have been evaluated in accordance with requirements of ES60601-1 and IEC 60601-1-2. The iCOquit® Smokerlyzer® Carbon Monoxide Monitor performed as intended, meeting the necessary requirements of these standards and is considered safe.

Software Verification and Validation Testing

The software for iCOquit® Smokerlyzer® is considered a "Moderate" level of concern. Testing and documentation as specified within FDA Guidance "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005*)" has been performed and supplied.

Bench Testing

Bench testing was performed with the iCOquit® Smokerlyzer® Carbon Monoxide Monitor to verify the performance to specifications of the proposed device. Testing includes:

- ES60601-1
- IEC 60601-1-2
- IEC 60601-1-11
- Software verification and system validation

Usability/Human Factors

Human Factors validation testing was performed with the iCOquit® Smokerlyzer® Carbon Monoxide Monitor by means of summative usability testing. This assessed an untrained lay user group's ability to comprehend use of the device effectively. The group selected was carefully chosen to represent the intended user and successfully demonstrated that lay users were able to understand their CO measurement and effectively use the iCOquit® Smokerlyzer® in accordance with its Intended Use.

VIII. CONCLUSIONS

Discussion of Differences

The differences and similarities between the subject and predicate device include:

- Subject device improves on the accuracy range
- Subject and predicate device display levels of CO in breath through an App paired with the devices. The predicate device can also relay results through an integrated screen on the handheld monitor
- Subject and Predicate performance specifications are similar
- Subject device offers a calculation from users PPM result in %COHb.

These differences do not raise any new concerns of safety or effectiveness and therefore the subject device can be considered similar.

Conclusion

The iCOquit® Smokerlyzer® Carbon Monoxide Monitor and the predicate device cleared under K171408 can be considered the same in their use of technology, design, features and intended use. The conclusions drawn from the nonclinical tests demonstrate that the proposed subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.