March 2, 2018

MD Diagnostics Limited
Glen Hillsley
Regulatory Affairs
15 Hollingworth Court, Turkey Mill
Maidstone, Kent, ME14 5PP
UNITED KINGDOM

Re: K171129
Trade/Device Name: Carbon Monoxide Monitors (CO Check Pro & CO Screen)
Regulation Number: 21 CFR 868.1430
Regulation Name: Carbon Monoxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCJ
Dated: January 29, 2018
Received: February 1, 2018

Dear Glen Hillsley:

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. 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K171129

Device Name
Carbon Monoxide monitors (CO Check Pro & CO Screen)

Indications for Use *(Describe)*
For monitoring of carbon monoxide in adult exhaled breath. They are for use in smoking cessation programs and can be used for the screening of CO poisoning and smoke inhalation. Also can be used for ambient air monitoring. For use by healthcare professionals only in professional healthcare facilities.

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.

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510(k) SUMMARY

MD Diagnostics Ltd. – Carbon monoxide monitors

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Contact Person: Glen Hillsley
Date Prepared: March 1, 2017

Candidate Device details

Proprietary/Trade name: Carbon monoxide monitors (CO Check Pro & CO Screen)

Common or Usual Name: Carbon Monoxide Gas Analyzer.

Classification Name: Carbon Monoxide Gas Analyzer, 21 C.F.R. § 868.1430.

Device classification: II

Product code: CCJ

Classification Panel: Anesthesiology

Predicate Device details

Predicate 1: Device name / 510k: TABATABA CO TESTER (k080278)
Manufacturer: FIM Medical, France.

Predicate 2: Device name / 510k: MicroCO meter (k950197)

Manufacturer: Carefusion, USA

Further to a review of the MAUDE database, from 1970 to the present day – There is no record of any product problems or safety issues relating to the use carbon monoxide gas analyzers.

Device Description

The Carbon monoxide monitors (CO Check Pro & CO Screen) are hand held, battery powered, carbon monoxide analyzers, used for monitoring the concentration of carbon monoxide in adult exhaled breath, typically for use in smoking cessation programs and for the screening of CO poisoning.

The devices are controlled via a two button keypad with the measured parameters displayed on a simple LCD with coloured lights and an accompanying buzzer sound in response to the CO level.

Electrochemical sensor technology is utilized to sample the gas and a microprocessor converts the output from the sensor into a meaningful displayed result, either as carbon monoxide in parts per million (CO) or the percentage of carboxyhaemoglobin in the blood (%COHb).

The breath sampling system that attaches directly to the carbon monoxide monitors, comprises of a non-patient contacting mouthpiece adapter incorporating a one way valve to prevent cross contamination and a single use, patient contacting cardboard mouthpiece. The mouthpiece adapter maybe replaced or reused as required.

The Carbon monoxide monitors are supplied non sterile for use by healthcare professionals only and can also be used for ambient air monitoring.

Intended Use / Indications for Use

The Carbon monoxide monitors are used to measure the concentration of carbon monoxide in exhaled breath

The devices are indicated for:

> For monitoring of carbon monoxide in adult exhaled breath. They are for use in smoking cessation programs and can be used for the screening of CO poisoning and smoke inhalation. Also can be used for ambient air monitoring. For use by healthcare professionals only in professional healthcare facilities.

Comparison of Technological Characteristics with the Predicate Device Substantial Equivalence Determination

Measurement of carbon monoxide in exhaled breath for use in smoking cessation programs and for screening for CO poisoning is the technological principle for both the candidate and predicate devices.

The MD Diagnostics Carbon monoxide monitors are substantially equivalent to the predicate devices, in terms of intended use, indications for use, technological characteristics, principle of operation, materials and performance characteristics to the cleared TABATABA CO tester covered

under k080278 and the MicroCO covered under K950197. Any minor differences in this section do not raise any different questions of safety and effectiveness.

Item	Candidate device – MD Diagnostics – Carbon monoxide monitors (CO Check Pro & CO Screen)	Predicate device – FIM Medical – TABATABA CO tester	Predicate device – Carefusion – MicroCO meter
Intended use	Measurement of Carbon monoxide in parts per million (PPM) and Carboxyhaemoglobin (%COHb) in exhaled breath.	SAME	SAME
Indications for Use	For monitoring of carbon monoxide in adult exhaled breath. They are for use in smoking cessation programs and can be used for the screening of CO poisoning and smoke inhalation. Also can be used for ambient air monitoring. For use by healthcare professionals only in professional healthcare facilities	SIMILAR, The CO Screen indications statement is the same as the predicate with the exception of explicitly stating the device is for use in adults and in professional healthcare facilities. These minor additions do not change the intended use compared to the predicate.	The predicate indications are not stated. However, the CO Check Pro has the same intended use as the predicate and similar indications as the predicate TABATABA.
Environments used	Professional healthcare facilities	SAME	SAME
Sensor	Electrochemical fuel cell	SAME	SAME
Human Factor	Hand held, two button operated with screen instructions via LCD.	SAME	Slide switch operation
Patient breath sampling system	Disposable Cardboard mouthpiece and plastic mouthpiece adapter	Disposable Plastic mouthpiece	SAME
Enclosure material	ABS	SAME	SAME
CO measurement range	0 to 99 ppm (CO Check Pro) 0 to 375ppm (CO Screen)	0 to 500 ppm	0 to 100ppm
Accuracy	+/- 2ppm or 5%, whichever is greater (CO Check Pro) +/- 3% (CO Screen)	+/- 5ppm	+/- 1ppm or 5%, whichever is greater
Power source	1 x Battery 9V, PP3	2 x Battery AA	SAME

Performance Data

The following performance data was provided in support of the substantial equivalence determination:

Biocompatibility Evaluation

The biocompatibility assessment for the Carbon monoxide monitors and its operational accessories was conducted in accordance with International Standard ISO 10993-1 - Biological Evaluation of the Medical Devices, Part 1 – Evaluation and testing in the risk management process as recognized by FDA. The Evaluation criteria considered the Cytotoxicity, Sensitization and Irritation aspects only.

Electrical Safety and ElectroMagnetic Compatibility Testing

Electrical Safety testing, to establish the basic safety and essential performance of the device and also EMC testing, to establish the emissions and immunity characteristics, was conducted on the CO Check Pro in accordance with IEC60601-1 and IEC60601-1-2 standards respectively.

Performance testing

Performance testing on the Carbon monoxide monitors was conducted to verify the devices' functionality across their operational ranges. This comprises of:
a) Gas performance testing – using known calibrated gases, to demonstrate the linearity and repeatability of CO ppm readings recorded across the device measurement ranges (20ppm, 50ppm, 100ppm & 375ppm – CO Screen only), with an acceptance criteria of +/- 2ppm or 5% (CO Check Pro) and +/-3% (CO Screen). The test results obtained were within +/- 2ppm for each measurement point.
b) Temperature testing – to demonstrate that the device operates successfully across the environment operating temperature range for the device. c) Packaging testing – to demonstrate the robustness of the device housing via a series of drop tests and the ability to function as intended thereafter.

Conclusion

The Carbon monoxide monitors are considered as safe and as effective as the predicate devices and are manufactured to a similar basic specification as the predicate devices. The Performance data demonstrates that the devices are fit for purpose and the results observed were as expected and in accordance with recognized standards.

The Carbon monoxide monitors have the same intended use, indications for use, principles of operation and virtually identical technological characteristics as the predicate devices. Due to the similarities, it's considered that the minor technical differences between the Carbon monoxide monitors and its predicate devices' do not raise any different questions of safety or effectiveness.

Thus, the Carbon monoxide monitors are considered substantially equivalent to the predicate devices.