November 10, 2022

Meridian Bioscience Israel Ltd.
Raffi Werner
VP Meridian Bioscience Israel
4 Ha'Maayan St
Modiin, 7177872
Israel

Re: K223185
Trade/Device Name: BreathID® Smart System
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter Fetus Serological Reagents
Regulatory Class: Class I, reserved
Product Code: MSQ, JJQ
Dated: October 6, 2022
Received: October 12, 2022

Dear Raffi Werner:

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,

Ribhi Shawar -S

Ribhi Shawar, Ph.D. (ABMM)
Branch Chief
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
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)*

Device Name
BreathID Hp Lab System and BreathID Smart System

Indications for Use *(Describe)*
The BreathID Hp Lab System or BreathID Smart System is intended for use to non-invasively measure changes in the 13CO2/12CO2 ratio of exhaled breath, which may be indicative of increased urease production associated with active Helicobacter pylori (H. pylori) infection in the stomach.
The BreathID Hp Lab System or BreathID Smart System is indicated for use as an aid in the initial diagnosis and post treatment monitoring of H. pylori infection in adult patients and pediatric patients ages 3-17 years old. The BreathID Hp Lab System consists of the appropriate IDkit Hp kit, and the BreathID Hp device, Auto Sampler and Lab Application. The BreathID Smart System consists of the appropriate IDkit Hp kit and the BreathID Smart device.
To be administered by trained personnel as ordered by a licensed healthcare practitioner.

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) Summary

Purpose of this 510(k):

The purpose of this Special 510(k) submission is to obtain marketing clearance for a modified configuration of the already cleared BreathID® Smart System (K220494). The modified configuration of the cleared BreathID® Smart System supports Windows 10 Operating System while the predicate device supports Windows CE 6 Operating System. The cleared BreathID® Smart System and the modified configuration have the same Intended Use and Indication for Use.

Applicant's Name

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Contact Person

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Date Prepared

Oct 02, 2022

Trade Name

BreathID® Smart System

Classification Name

Test, urea (breath or blood)

Product Code

MSQ, JJQ

Device Class

I

Regulation Number

866.3110

Panel

Microbiology

Predicate Device

BreathID® Smart System [Meridian Bioscience Israel Ltd.] cleared under K220494

Device Description

The modified BreathID® Smart System, is a non-invasive breath test system for detecting the presence of *Helicobacter pylori* (*H. pylori*). The system consists of an electro-optical medical device with embedded software designed to measure and compute the changes in the ratio between $^{13}CO_2$ and $^{12}CO_2$ concentrations in the patient's exhalation, an integrated Auto Sampler, integrated software, and a test kit.

The IDkit Hp® Two test kit consists of:

- One 75mg ^{13}C-urea tablet
- One packet of 4.3g of powdered Citrica (citric acid)
- One drinking straw
- One drinking cup
- One Package Insert (Instructions for Use)
- One Quick User Guide
- Two Breath Sample Bags (one Baseline and one Post Ingestion)
- Four bar code labels
- A large Sample Transport Bag

Using bags for breath collection enables off-site and deferred testing as well as testing of multiple breath sample bags sequentially in a batch. The modified BreathID® Smart System measures and computes the ratio between $^{13}CO_2$ and $^{12}CO_2$ in the patient's exhaled breath before and after the ingestion of ^{13}C-urea. The change in the $^{13}CO_2$ / $^{12}CO_2$ ratio before and after ingestion of ^{13}C-urea is used to compute the Delta over Baseline (DOB).

The ^{13}C measurement method for both the subject and the cleared (predicate) versions of the BreathID® Smart System is based on Molecular Correlation Spectroscopy™ (MCS) technology. MCS technology is based on the concept of optical absorption of specific radiation emitted from CO_2 discharge lamps.

Intended Use / Indication for Use

The BreathID® Hp Lab System or the BreathID® Smart System[1] is intended for use to non-invasively measure changes in the $^{13}CO2/^{12}CO2$ ratio of exhaled breath, which may be indicative of increased urease production associated with active *Helicobacter pylori* (*H. pylori*) infection in the stomach.

The BreathID® Hp Lab System or BreathID® Smart System is indicated for use as an aid in the initial diagnosis and post treatment monitoring of *H. pylori* infection in adult patients and pediatric patients ages 3-17 years old. The BreathID® Hp Lab System consists of the appropriate IDkit Hp® kit, and the BreathID® Hp device, Auto Sampler and Lab Application. The BreathID® Smart System consists of the appropriate IDkit Hp® kit and the BreathID® Smart device.

To be administered by trained personnel as ordered by a licensed healthcare practitioner.

Substantial Equivalence Discussion

Comparison of Intended Use

The intended use of the modified BreathID® Smart System, has remained equivalent to the predicate device; both are intended for the initial diagnosis and post treatment monitoring of *H. pylori* infection in adult and pediatric (ages 3-17 years old) patients, and both are prescription devices. Both devices are designed for performing multiple $^{13}CO_2$ based breath tests automatically one after the other.

[1] The BreathID® Smart System and BreathID® Hp Lab System share the same Intended Use and Indications for Use as cleared in K220494.

Test Kit and Ingested Drug

The modified BreathID® Smart System and the predicate BreathID® Smart System both use the same IDkit Hp® Two kit that consists of ^{13}C urea, approved in NDA 21-314, and breath collection bags, cleared in K220494. The protocol for breath collection and ingestion of ^{13}C urea remains unchanged.

Comparison of Technological Characteristics

- The modified BreathID® Smart System shares with its predicate device the same measurement system based on the same technology, the same test kit, the same test substrate, and the same diagnostic capabilities. Both the subject and predicate systems use the MCS technology (Molecular Correlation Spectroscopy) and measure the ratio of $^{13}CO_2/^{12}CO_2$ in exhaled breath prior to and after administration of the test substrate (^{13}C-Urea). The MCS technology measures the light absorbance by infrared spectrometry, which is correlative to CO_2 concentration in the breath sample. The output result in both systems is the Delta Over Baseline (DOB) and a positive/negative determination is based on the same assay cut-off (>5 DOB).
- The modified device is based on the same analyzer and integrated auto sampler as the predicate, enabling four pairs of breath sample bags to be measured automatically and sequentially.
- The predicate device is based on a Control Unit with the Windows CE Operating System. In the modified device, the Control Unit was modified to support the Windows 10 Operating system and the BreathID® Smart application was modified to run on Windows 10.

Summary of Performance Testing

Meridian Bioscience has performed extensive and well executed verification and validation to verify the performance of the modified BreathID® Smart System. The verification and validation testing program for the modified BreathID® Smart System was designed based on the device specifications and requirements, as well as on the associated potential risks, as identified and evaluated in the risk analysis and in accordance with FDA recognized standards.

Software Verification and Validation

Software testing was conducted to evaluate the performance of the subject system and to verify that it performs according to its software requirements. Verification involved functionality testing,

timing analysis, integration with the hardware, and error detection and handling. Verification was achieved by design reviews, code walkthroughs, functional testing of sub-components and integration testing with the hardware.

System Performance

A comparison test between the predicate BreathID® Smart System and the modified BreathID® Smart System was conducted. The comparison test included 80 measurements on each system and statistically showed that both systems may be used interchangeably.

Safety Testing

Electrical safety and electromagnetic compatibility (EMC) tests were conducted by the Standards Institution of Israel. The BreathID® Smart System was found to comply with the requirements of the Safety and EMC standards.

The above tests used contrived gases for simulating different levels of $^{13}CO_2$ as a result of *H. pylori* infection. All the pre-defined acceptance criteria were met; therefore, it can be concluded that the modified BreathID® Smart System was verified to give accurate and repeatable results over time.

Conclusion:

The information submitted in this Special 510(k) premarket notification is complete and supports a finding of substantial equivalence.