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

June 23, 2022

Re: K220494
Trade/Device Name: BreathID Hp Lab System, BreathID Smart System
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter Fetus Serological Reagents
Regulatory Class: Class I, reserved
Product Code: MSQ
Dated: February 16, 2022
Received: February 22, 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,

Kristian Roth, Ph.D.
Deputy Director
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)*
K220494

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Special 510(k) Summary

Purpose of this 510(k)

The purpose of this Special 510(k) submission is to obtain marketing clearance for a labeling modification of the **BreathID® Hp Lab System** (K173777) and the **BreathID® Smart System** (K193610). This labeling modification is solely to the package insert which is included in the **IDkit Hp™ Two,** the test kit used as part of these two cleared 510(k) devices while the Intended Use and Indication for Use remain unchanged. The modified labeling informs clinicians that they may act upon positive results for the Urea Breath Test with the BreathID® Hp Lab System or the BreathID® Hp Smart System for patients taking proton pump inhibitors (PPIs), a family of prescription and over-the-counter drugs that help alleviate the symptoms caused by *H. pylori* infection.

Applicant's Name

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Date Prepared

June 10, 2022

Trade Name

BreathID® Hp Lab System; BreathID® Smart System

Classification Name

Test, urea (breath or blood)

Product Code

MSQ, JJQ

Device Class

I

Regulation Number

866.3110

Panel

Microbiology

Predicate Devices

BreathID® Hp Lab System [Meridian Bioscience Israel Ltd.] cleared under K173777

and

BreathID® Smart System [Meridian Bioscience Israel Ltd.] cleared under K193610

Device Description (unchanged from cleared devices)

The BreathID® Hp Lab System and the BreathID® Smart System are two non-invasive breath test systems for detecting the presence of *Helicobacter pylori* (*H. pylori*) based on the same technology. The systems consist of an electro-optical medical device 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 Auto Sampler, software, and a test kit.

The **IDkit Hp™ Two** test kit consists of:

- One 75mg ^{13}C-urea tablet
- One packet of 4.3g 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
- One 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 BreathID® Hp Lab System and the BreathID® Smart System measure and compute 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 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 (unchanged from cleared devices)

The BreathID® Hp Lab System or BreathID® Smart System is intended for use to non-invasively measure changes in the $^{13}CO_2/^{12}CO_2$ 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™ Two and the BreathID® Smart device.

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

Substantial Equivalence

The device and kit of the BreathID® Hp Lab System and the BreathID® Smart System that are subject of this Special 510(k) labeling modification request are identical to the device and kit of the cleared predicate BreathID® Hp Lab System (K173777) and the cleared predicate BreathID® Smart System (K193610). They use the exact same technology and the same principles of

operation, including the same test kit, utilizing the same test substrate and same method to collect patient's exhaled breath samples for the test, as the predicate devices.

There are additional minor changes to the Package Insert that did not require a 510(k) submission and that have been previously implemented in accordance with design control requirements as specified in 21 CFR 820.30 and based on FDA Guidance "Deciding When to Submit a 510(k) for a Change to an Existing Device", issued on October 25th, 2017.

The labeling modification in this submission is specifically related to the current limitation for those patients taking proton pump inhibitors (PPIs) and performing the breath test and is reflected in changes to the package insert of the test kit, IDkit Hp™ Two, that is used as part of the BreathID® Hp Lab System or the BreathID® Smart System. This labeling modification informs clinicians that they may act upon positive breath test results in patients using PPIs, a family of prescription and over-the-counter drugs that helps alleviate the symptoms caused by *H. pylori* infection. The changes in the Package Insert are described below:

1. In **Section 5.2 of the package insert "Warnings and Precautions"**, item 7 is revised to remove the following statement:

   "Antimicrobials, proton pump inhibitors, and bismuth preparations are known to suppress H. pylori. Ingesting these medications within two weeks prior to performing the breath test may produce false negative test results."

   The following statements will replace the removed warning:

   "False negative test results may be caused by:

   - *Ingestion of antimicrobials or bismuth preparations within two weeks prior to performing the breath test.*
   - *Ingestion of proton pump inhibitors (PPIs) within two weeks prior to performing the breath test.*

     Note: If a negative result is obtained from a patient ingesting a PPI within two weeks prior to the breath test, the results cannot be considered indicative of the absence of urease associated with H. pylori and the test should be repeated two weeks after discontinuing the PPI treatment. A positive result for a patient on a PPI could be considered as indicative of the presence of urease associated with H. pylori."

2. In **Section 7.4 of the package insert "Operational Precautions and Limitations",** item 4 is revised and items 5 and 6 are added to accept positive breath test results in patients using PPIs as follows:

"4. The patient should not have taken antimicrobials, proton pump inhibitors (PPI) or bismuth preparations within two weeks prior to administering the test.

5. If the test is negative and it is determined that the subject has used PPIs within two weeks prior to taking the breath test, the test may provide a false negative result. The test needs to be repeated two weeks post discontinuation of PPI treatment.

6. A positive result for a patient on PPI could be considered as indicative of the presence of urease enzyme associated with H. pylori."

3. **Section 8.1 of the package insert "Patient Preparation"** is revised to accept positive breath test results in patients using PPIs as in the following statement:

"The patient should have fasted at least one hour before administering the solution. The patient should not have taken antimicrobials, proton pump inhibitors (PPI) or bismuth preparations within two weeks prior to administering the test. If PPIs are used within two weeks of breath testing, false negative test results may occur, and the test should be repeated two weeks after discontinuation of PPI treatment. A positive result for a patient on PPI could be considered as indicative of the presence of urease enzyme associated with H. pylori."

Test Kit and Ingested Drug

The IDkit Hp™ Two test kit that includes the ^{13}C urea tablet and citric acid powder approved in NDA-21-314, the procedure for ingestion of test substrate, and the breath collection method remain unchanged. The drinking cup has been changed to a drinking cup with a lid, thereby providing a more efficient means of dissolving the substrate, by sealing the cup and shaking it.

Comparison of Technological Characteristics

Technological characteristics remain unchanged.

Summary of Performance Testing

Performance characteristics remain unchanged.

Conclusion:

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