December 19, 2022

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

Re: K221896
Trade/Device Name: BreathID Hp System
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter Fetus Serological Reagents
Regulatory Class: Class I, reserved
Product Code: MSQ, JJQ
Dated: June 28, 2022
Received: June 30, 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.

Please note that if you modify your IVD in the future to exceed any of the limitations to the exemption found in 21 CFR 866.9(c), your device will require a new 510(k) prior to marketing this device in the United States and will not be exempt from the premarket notification requirements so long as it exceeds the limitations to the exemption found in 21 CFR 866.9.

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
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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)*
K221896

Device Name
BreathID® Hp System

Indications for Use *(Describe)*
The BreathID® Hp System is intended for use to continually and 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 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 System consists of the appropriate IDkit Hp® kit and the BreathID® Hp test device.
The device is for use by trained health care professionals. To be administered under a physician's supervision.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 System** (K173772). This labeling modification is solely to the package insert which is included in the **IDkit Hp® One,** the test kit used as part of this cleared 510(k) device, while the Intended Use and Indication for Use remain unchanged. The modified labeling informs clinicians that for patients taking proton pump inhibitors (PPIs), a positive result could be considered as indicative of the presence of urease enzyme associated with *H. pylori*. PPIs are 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 28, 2022

Trade Name

BreathID® Hp System

Classification Name

Test, urea (breath or blood)

Product Code

MSQ, JJQ

Device Class

I

Regulation Number

866.3110

Panel

Microbiology

Predicate Device

BreathID® Hp System [Meridian Bioscience Israel Ltd.] cleared under K173772.

Device Description (unchanged from cleared device)

The BreathID® Hp System is a non-invasive breath test system for detecting the presence of *Helicobacter pylori* (*H. pylori*). 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, software, and a test kit.

The **IDkit Hp® One** test kit consists of:

- One Package Insert
- One Tablet of ^{13}C-enriched urea,75mg
- One packet of 4.3g of Powder Citrica (citric acid).
- One IDcircuit™ nasal cannula
- One straw for stirring and drinking

Using a nasal cannula for breath collection directly from the patient's nostrils enables point of care testing. The BreathID® Hp continually 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 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 device)

The BreathID® Hp System is intended for use for continually and 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 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 System consists of the appropriate IDkit Hp® kit, and the BreathID® Hp test device. The device is for use by trained health care professionals. To be administered under a physician's supervision.

Substantial Equivalence

The device and kit of the BreathID® Hp System that is subject of this Special 510(k) labeling modification request is identical to the device and kit of the cleared predicate BreathID® Hp System (K173772). The exact same technology and the same principles of operation are used, 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 device.

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® One that is used as part of the BreathID® Hp System. This labeling modification informs clinicians that a positive result could be considered as indicative of the presence of urease enzyme associated with *H. pylori* 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 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, it may be a false-negative result 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 7.7 Operational Precautions and Limitations,** item 4-6 is revised to accept positive breath test results in patients using PPIs as is in the following statement:

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

   Note: The numbering of the next items in this section was adjusted accordingly.

3. **Section 8.1 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® One 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.

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.