SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY

I Background Information:

A 510(k) Number

K221896

B Applicant

Meridian Bioscience Israel Ltd.

C Proprietary and Established Names

BreathID Hp System

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
MSQ, JJQ	Class I, reserved	21 CFR 866.3110 - Campylobacter Fetus Serological Reagents	MI - Microbiology

II Review Summary:

This 510(k) submission contains information/data modifications made to the Meridian's own Class I device requiring 510(k). The following items are present and acceptable.

1. The name and 510(k) number of the submitter's previously cleared device are provided.

2. Meridian's statement that the **INDICATIONS FOR USE/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed. This change was for the removal of a limitation**. The sponsor wanted to remove a limitation stating, all test subjects need to refrain PPI drugs for two

weeks prior to testing. The new limitation will state, subjects who get a positive result while on PPIs should be considered positive and a positive result is an actionable result, while a negative result is not actionable and subjects suspected of *H. pylori* infection should be retested after PPI have been ceased for at least two weeks, prior to re-testing.

4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics were provided.

5. A Design Control Activities Summary includes:

   a) The risk associated with the removal of a limitation form the package insert was mitigated by the addition of another limitation stating, "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."

   b) Following modifications were included in sections of the package insert as follows:

      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 replaced the removed warning:

      7. 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*.

      Section 7.7 Operational Precautions and Limitations, item 4-6 is revised to accept positive breath test results in patients using PPIs as noted in the following statements:

      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 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*.

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*.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in the special 510(k) submission and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.