November 4, 2018

Meridian Bioscience, Inc.
Jack Rogers
Director of Regulatory Affairs and Design Assurance
3471 River Hills Drive
Cincinnati, Ohio 45244

Re: K182559
Trade/Device Name: PREMIER Platinum HpSA PLUS
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter fetus serological reagents
Regulatory Class: Class I
Product Code: LYR
Dated: September 14, 2018
Received: September 17, 2018

Dear Jack Rogers:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Steven R. Gitterman -S for

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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)*
K182559

Device Name

PREMIER Platinum HpSA® PLUS

Indications for Use *(Describe)*

The PREMIER Platinum HpSA PLUS enzyme immunoassay (EIA) is an in vitro qualitative procedure for the detection of Helicobacter pylori antigens in human stool. Test results are intended to aid in the diagnosis of H. pylori infection and to monitor response during and post-therapy in patients. Accepted medical practice recommends that testing by any current method, to confirm eradication, be done at least four weeks following completion of therapy.

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

510(k) number: K182559 **Date of Preparation:** October 30, 2018

Owner: **Meridian Bioscience, Inc.**
3471 River Hills Drive
Cincinnati, Ohio 45244 USA
Phone: (513) 271-3700
Fax: (513) 272-5213

Contact: **Primary Contact:**
Jack Rogers
Director, Regulatory Affairs & Design Assurance

Secondary Contact:
Charles G. Thornton
Vice President, Regulatory Affairs and Quality Assurance

Trade Name: **PREMIER Platinum HpSA® PLUS**

Common Name: Helicobacter Pylori

Classification Name: *Campylobacter fetus* serological reagents
(21 CFR 866.3110, Product Code LYR)

Predicate Device: **PREMIER Platinum HpSA® PLUS**
K053335

Device Description

The PREMIER Platinum HpSA® PLUS test is a microwell-based enzyme immunoassay that detects *H. pylori* antigens present in human stool. The test utilizes a plurality (mixture) of monoclonal anti-*H. pylori* capture antibodies adsorbed to microwells. Diluted patient samples and an enzyme conjugate reagent are added to the microwells and incubated for one hour at room temperature. A wash is performed to remove unbound material. Substrate is added and incubated for 10 minutes at room temperature. Color develops in the presence of bound enzyme. Stop solution is added and the results are interpreted visually or spectrophotometrically. No calculations are required and the visual color change makes the interpretation of results objective and simple.

In addition, the HpSA test permits assessment of established or novel anti-*H. pylori* treatment during and post-therapy to monitor for treatment effectiveness, relapse or eradication.

PREMIER Platinum HpSA PLUS (K053335), as the predicate device for this submission, was a modification of PREMIER Platinum HpSA (K983255, K980076) that provided increased signal strengths with positive test results and better discrimination between low positive and negative tests. This submission is for modifications to the antibodies used in the microwells and conjugate reagent.

Intended Use / Indications for Use

The PREMIER Platinum HpSA PLUS enzyme immunoassay (EIA) is an in vitro qualitative procedure for the detection of *Helicobacter pylori* antigens in human stool. Test results are intended to aid in the diagnosis of *H. pylori* infection and to monitor response during and post-therapy in patients. Accepted medical practice recommends that testing by any current method, to confirm eradication, be done at least four weeks following completion of therapy.

Predicate Device Comparison

Similarities Between the Modified Device and the Predicate Device		
	MODIFIED DEVICE PREMIER Platinum HpSA® PLUS	**PREDICATE DEVICE PREMIER Platinum HpSA® PLUS K053335**
Intended Use / Indications for Use	The PREMIER Platinum HpSA® PLUS in an in vitro diagnostic procedure for the detection of *Helicobacter pylori* antigens in human stool. Test results are intended to aid in the diagnosis of *H. pylori* infection and to monitor response during and post-therapy in patients. Accepted medical practice recommends that testing by any current method, to confirm eradication, be done at least four weeks following completion of therapy.	The PREMIER Platinum HpSA® PLUS in an in vitro diagnostic procedure for the detection of *Helicobacter pylori* antigens in human stool. Test results are intended to aid in the diagnosis of *H. pylori* infection and to monitor response during and post-therapy in patients. Accepted medical practice recommends that testing by any current method, to confirm eradication, be done at least four weeks following completion of therapy.
Technology	Qualitative Enzyme Immunoassay (EIA), Microwell Format	Qualitative Enzyme Immunoassay (EIA), Microwell Format
Interpretation of Results	Visual or Spectrophotometric	Visual or Spectrophotometric
Performance Characteristics		
Analytical Sensitivity (LoD)	≥ 4.66 ng *H. pylori* protein/mL of stool	≥ 4.67 ng *H. pylori* protein/mL of stool
Sensitivity	PPA: 100%	PPA: 100%
Specificity	NPA: 100%	NPA: 94.8%

Differences Between the Modified Device and the Predicate Device		
	MODIFIED DEVICE **PREMIER Platinum HpSA® PLUS**	**PREDICATE DEVICE** **PREMIER Platinum HpSA® PLUS** **K053335**
Crossreactivity	The specificity of the modified PREMIER Platinum HpSA PLUS was tested by utilizing the following bacterial or viral strains. Positive and negative stools were spiked with 1.0 x 10^7 CFU/mL (bacteria or fungi) or a final concentration greater than 1 x 10^5 $TCID_{50}$/mL (viruses) and tested by the modified PREMIER Platinum HpSA PLUS. None of the organisms affected positive or negative test results. **Microorganism or virus** Adenovirus 41, *Aeromonas hydrophila, Bacillus subtilis, Borrelia burgdorferi, Campylobacter coli, Campylobacter fetus, Campylobacter jejuni, Campylobacter lari, Candida albicans, Citrobacter freundii, Clostridium difficile, Clostridium perfringens, Enterobacter cloacae, Enterococcus faecalis, Escherichia coli* O157:H7, *Escherichia coli, Escherichia coli 8739, Escherichia coli 9637, Escherichia fergusonii, Escherichia hermanii, Escherichia hermanii EMDI-64 Haemophilus influenzae, Klebsiella pneumoniae, Lactococcus lactis, Listeria monocytogenes, Peptostreptococcus anaerobius, Proteus vulgaris, Pseudomonas aeruginosa, Pseudomonas fluorescens,* Rotavirus, *Salmonella dublin, Salmonella hilversum*, *Salmonella heidelberg* (Group B), *Salmonella minnesota*, *Salmonella typhimurium, Serratia liquefaciens, Serratia marcescens, Shigella boydii, Shigella dysenteriae, Shigella flexneri, Shigella sonnei, Staphylococcus aureus, Staphylococcus aureus* (Cowan Strain I), *Staphylococcus epidermidis, Yersinia enterocolitica*	The specificity of Premier Platinum HpSA PLUS was tested by utilizing the following bacterial or viral strains. Positive and negative stools were spiked with ≥ 1.2 X 10^9 bacterial or yeast organisms/mL and tested by Premier Platinum HpSA PLUS. The concentration of viral organisms was not calculated. None of the organisms affected positive or negative test results. **Microorganism or virus** *Adenovirus, Aeromonas hydrophila, Campylobacter lari, Campylobacter fetus, Campylobacter jejuni, Campylobacter jejuni 2, Campylobacter jejuni solution, Candida albicans, Citrobacter freundii, Clostridium difficile, Clostridium perfringens, Enterobacter cloacae, Enterococcus faecalis, Escherichia coli O157:H7, Escherichia coli 8739, Escherichia coli 9637, Escherichia fergusonii, Escherichia hermanii, Escherichia hermanii EMDi-64, Klebsiella pneumonia, Lactobacillus lactis, Listeria monocytogenes, Peptostreptococcus anaerobius , Proteus vulgaris, Pseudomonas aeruginosa, Pseudomonas fluorescens,* Rotavirus, *Salmonella Group B, Salmonella typhimurium, Serratia liquefaciens, Serratia marcescens, Shigella boydii, Shigella flexneri, Shigella dysenteriae, Shigella sonnei, Staphylococcus aureus, Staphylococcus aureus (Cowans 1), Staphylococcus epidermidis, Streptococcus faecalis, Salmonella enterica serovar Hilversum, Salmonella enterica subsp. Enterica serovar Hilversum, Salmonella enterica subsp. Enterica serovar Minnesota, Yersinia enterocolitica*
Interfering Substances	The following substances, that may be present in human stool, do not interfere with positive or negative test results at the stated concentrations per 500 µl human stool: • Barium sulfate – 25 mg • Mylanta – 11.5 mg • Pepto-Bismol – 0.44 mg • Prilosec OTC – 1 mg • Tagamet – 1 mg • TUMS – 10 mg • Hemoglobin – 62.5 mg • Mucin – 17 mg • NSAID Ibuprofen – 0.25 mg • Stearic acid – 5.3 mg • Palmitic acid – 2.65 mg • White blood cells – 250 uL • Whole blood – 250 uL	The following substances, that may be present in human stool do not interfere with positive or negative test results at the stated concentrations, per 500 µl human stool: • Barium sulfate - 10mg • Mylanta - 0.84mg • Pepto-Bismol - 0.35mg • Prilosec OTC - 1mg • Tagamet - 1mg • TUMS - 10mg • Human Hemoglobin (i.e. dark stool) - 15 mg • Mucin - 6.7mg • Steric + Palmitic Acids (i.e. Fatty stool) - 7.9mg • Whole Blood - 100 µl

NON-CLINICAL PERFORMANCE DATA

Analytical Performance

Reproducibility

Assay precision, intra-assay variability and inter-assay variability were assessed with a reference panel prepared from moderately positive samples (n=3), low positive samples (n=3), high negative samples (n=3) and a true negative sample (n=1). In addition, the positive and negative kit controls were run when each panel was tested. Each panel was tested once a day by two technicians, at three different laboratory sites, for 5 consecutive days. Overall, 100% (300/300, 98.7-100%, 95% CI) of results obtained with the PREMIER Platinum HpSA PLUS were as expected. There were no invalid results generated during the study (0.0%; 0/300; 0.0-1.3%, 95% CI).

Analytical Sensitivity

Analytical sensitivity studies were performed to determine the analytical limit of detection (LoD) for the modified PREMIER Platinum HpSA® PLUS. The limit of detection is defined as the first dilution containing the target organism that produces positive results approximately 95% of the time. Three lots of the modified assay were evaluated.

The limit of detection for the PREMIER Platinum HpSA PLUS assay was determined to be 4.66 ng/mL.

Analytical Specificity

Cross-Reactivity:

The specificity of PREMIER Platinum HpSA PLUS was tested by utilizing the following bacterial or viral strains. Potentially cross-reactive microorganisms were added at a target concentration of 1.0×10^7 CFU/mL (bacteria or fungi), or a concentration greater than 1×10^5 $TCID_{50}$/mL (viruses), to a natural negative and a contrived positive sample. None of the organisms affected positive or negative test results.

Microorganism or virus

Adenovirus 41, *Aeromonas hydrophila, Bacillus subtilis, Borrelia burgdorferi, Campylobacter coli, Campylobacter fetus, Campylobacter jejuni, Campylobacter lari, Candida albicans, Citrobacter freundii, Clostridium difficile, Clostridium perfringens, Enterobacter cloacae, Enterococcus faecalis, Escherichia coli O157:H7, Escherichia coli, Escherichia coli 8739, Escherichia coli 9637, Escherichia fergusonii, Escherichia hermanii, Escherichia hermanii EMDI-64, Haemophilus influenzae, Klebsiella pneumoniae, Lactococcus lactis, Listeria monocytogenes, Peptostreptococcus anaerobius, Proteus vulgaris, Pseudomonas aeruginosa, Pseudomonas fluorescens,* Rotavirus, *Salmonella dublin, Salmonella hilversum*, *Salmonella heidelberg* (Group B), *Salmonella minnesota, Salmonella typhimurium, Serratia liquefaciens, Serratia marcescens, Shigella boydii, Shigella dysenteriae, Shigella flexneri, Shigella sonnei, Staphylococcus aureus, Staphylococcus aureus (Cowan Strain I), Staphylococcus epidermidis* and *Yersinia enterocolitica*

Interfering Substances:

The following substances, that may be present in human stool, do not interfere with positive or negative test results at the stated concentrations per 500 uL human stool: Barium sulfate – 25 mg, Mylanta – 11.5 mg, Pepto-Bismol – 0.44 mg, Prilosec (omeprazole) – 1 mg, Tagamet (cimetidine) – 1 mg, TUMS – 10 mg, Hemoglobin – 62.5 mg, Mucin – 17 mg, NSAID Ibuprofen – 0.25 mg, Stearic acid – 5.3 mg, Palmitic acid – 2.65 mg, White blood cells – 250 uL, Whole blood – 250 uL.

CLINICAL PERFORMANCE DATA

Clinical Study

Comparison of Modified PREMIER Platinum HpSA PLUS to PREMIER Platinum HpSA PLUS (Predicate)

One hundred and fifty-nine (159) archived, unpreserved stool samples from symptomatic patients were analyzed for *H. pylori* antigen by the modified PREMIER Platinum HpSA PLUS and PREMIER Platinum HpSA PLUS (Predicate) to demonstrate that changes to the microwell and conjugate antibodies do not affect assay performance. The performance of the modified PREMIER Platinum HpSA PLUS was substantially equivalent to the predicate device, generating 100% positive percent agreement and 100% negative percent agreement with 95% confidence intervals of 93.7-100.0% and 96.4-100.0%, respectively.

	PP HpSA PLUS (Predicate)		
Modified PP HpSA PLUS	**Positive**	**Negative**	**Total**
Positive	57	0	57
Negative	0	102	102
Total	57	102	159
			95% CI
Positive Agreement	57/57	100.0%	93.7-100.0%
Negative Agreement	102/102	100.0%	96.4-100.0%

CONCLUSION

The modified PREMIER Platinum HpSA® PLUS assay is substantially equivalent to the predicate device.