August 21, 2018

TECHLAB, Inc.
Donna Link
Director Regulatory and Compliance
2001 Kraft Drive
Corporate Research Center
Blacksburg, Virginia 24060

Re: K181400
Trade/Device Name: H. Pylori Chek
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter fetus serological reagents
Regulatory Class: Class I
Product Code: LYR
Dated: May 24, 2018
Received: May 29, 2018

Dear Donna Link:

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 post marketing 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,

Ribhi Shawar -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)*
K181400

Device Name
H. PYLORI CHEK

Indications for Use *(Describe)*

The TECHLAB H. PYLORI CHEK™ test is an enzyme immunoassay for the qualitative detection of Helicobacter pylori specific antigen. It is intended for use with human fecal specimens to aid in the diagnosis of H. pylori infection and to demonstrate loss of H. pylori antigen following treatment. The test can be used with unpreserved fecal specimens and fecal specimens preserved in transport media from patients suspected of H. pylori infection. Testing of patients to demonstrate loss of H. pylori antigen following treatment should be performed no sooner than 4 weeks after completion of the treatment regimen. Test results should be taken into consideration by the physician in conjunction with the patient history and symptoms.

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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***H. PYLORI CHEK*™ 510(k) SUMMARY**

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

Applicant/Contact Information:

Date Prepared:	August 20, 2018
Name:	TECHLAB, Inc.
Address:	2001 Kraft Drive Corporate Research Center Blacksburg, VA 24060 USA
Contact Person:	Donna T. Link
Phone Number:	540-953-1664
Email:	dlink@techlab.com

1.1 Manufacturing Facility Address

TECHLAB, Inc.
20 Corporate Drive
Radford, VA 24141 USA

1.2 Product and Trade Name of the Device

H. PYLORI CHEK™

1.3 Common Name or Classification Name

H. pylori detection test

1.4 Classification and Regulation

Class I
21 CFR 866.3110; *Campylobacter fetus* serological reagents

1.5 Product Code

LYR – *Campylobacter pylori*

1.6 Panel

83 Microbiology

1.7 Reason for Premarket Notification

The development of a new enzyme immunoassay for the qualitative detection of *H. pylori* specific antigen.

Intended Use

The TECHLAB® *H. PYLORI CHEK*™ test is an enzyme immunoassay for the qualitative detection of *Helicobacter pylori* specific antigen. It is intended for use with human fecal specimens to aid in the diagnosis of *H. pylori* infection and to demonstrate loss of *H. pylori* antigen following treatment. The test can be used with unpreserved fecal specimens and fecal specimens preserved in transport media from patients suspected of *H. pylori* infection. Testing of patients to demonstrate loss of *H. pylori* antigen following treatment should be performed no sooner than 4 weeks after completion of the treatment regimen. Test results should be taken into consideration by the physician in conjunction with the patient history and symptoms.

Explanation

It is estimated that half of the global population is infected with *H. pylori*. The majority of those infected remain asymptomatic and do not require treatment (colonized individuals). A minority of infected individuals develop gastritis, and a fraction of those further develop gastric ulcers or gastric cancer. The diagnosis of *H. pylori* infection is endoscopy with biopsy – the biopsied tissue is tested for the presence of *H. pylori* by culture, histology, or rapid urease test. Under current guidelines, endoscopy is still recommended for the diagnosis of *H. pylori* infection in patients with alarm symptoms (e.g. GI bleeding, sudden weight loss, excessive vomiting, anemia), or patients over the age of 55. However, for younger patients not exhibiting alarm symptoms, non-invasive tests such as the urea breath test (UBT) or fecal antigen test are recommended for diagnosis of *H. pylori* infection. Following completion of a treatment regimen of antibiotics and a proton pump inhibitor (PPI), it is recommended that patients be tested to verify eradication of *H. pylori* infection. Serum antibody tests are also available, but these are unable to distinguish between past and current infection. By detecting antigen present in fecal specimens, the *H. PYLORI CHEK*™ test allows for the non-invasive detection of *H. pylori* when endoscopy is not required.

Device Description

The *H. PYLORI CHEK*™ test uses antibodies specific to *H. pylori* antigen. The *Microassay Plate* in the kit contains immobilized capture antibodies against *H. pylori* antigen. The *Conjugate* consists of antibodies specific to *H. pylori* antigen conjugated to horseradish peroxidase. In the assay, an aliquot of a diluted fecal specimen is transferred to a microassay well containing the *Conjugate*. If the antigen is present in the specimen, it will bind to the *Conjugate* and to the immobilized capture antibody during the incubation phase. Any unbound material is removed during the washing steps. Following the addition of *Substrate*, a color is detected due to the enzyme-antibody-antigen complexes that formed in the presence of antigen.

Materials Provided

- ***Microassay Plate –*** *12 strips, each consisting of 8 wells coated with antibodies to H. pylori antigen (stored with desiccant)*
- ***Conjugate (7 mL) –*** *Antibodies to H. pylori antigen coupled to horseradish peroxidase in a buffered protein solution containing 0.05% ProClin® 300*
- ***Diluent (40 mL) –*** *Buffered protein solution containing 0.05% ProClin® 300. The Diluent is also to be used as the negative control solution.*
- ***Positive Control (3.5 mL) –*** *H. pylori antigen in a buffered protein solution containing 0.05% ProClin® 300*
- ***Stop Solution (7 mL) –*** *0.6 N sulfuric acid. CAUTION: Avoid contact with skin or eyes; flush with water immediately if contact occurs*
- ***Substrate (14 mL) –*** *solution containing tetramethylbenzidine and peroxide*

- ***Wash Buffer Concentrate (50 mL) –*** *20X concentrate containing phosphate buffered saline, detergent, and 0.2% thimerosal*

Accessories:
100 Disposable plastic transfer pipettes
2 Plastic adhesive sheets
1 Wash Solution Label
50 Wooden Applicator sticks

The predicate device (Premier® PLATINUM HPSA PLUS) and the *H. PYLORI CHEK*™ test use the same ELISA (enzyme linked immunosorbent assay) technology and are substantially equivalent in principle. The following tables show a comparison of both devices' similarities and differences.

Predicate Device Comparison Table Similarities		
Item	***H. PYLORI CHEK*™**	**Premier® Platinum HpSA® PLUS (K053335)**
Intended Use	The TECHLAB *H. PYLORI CHEK*™ test is an enzyme immunoassay for the qualitative detection of *Helicobacter pylori* specific antigen. It is intended for use with human fecal specimens to aid in the diagnosis of *H. pylori* infection and to demonstrate loss of *H. pylori* antigen following treatment. The test can be used with unpreserved fecal specimens and fecal specimens preserved in transport media from patients suspected of *H. pylori* infection. Testing of patients to demonstrate loss of *H. pylori* antigen following treatment should be performed no sooner than 4 weeks after completion of the treatment regimen. Test results should be taken into consideration by the physician in conjunction with the patient history and symptoms.	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.
Measured analyte	Detection of *H. pylori* antigen	Same
Type of Test	Qualitative	Same
Controls	Positive and negative control included in the kit	Same
Target Population	Persons suspected of having *H. pylori* infection	Same
Storage	Refrigerated (2°C – 8°C)	Same
Reading Method	Visual, Spectrophotometric	Same

There are no differences between the subject device and the predicate(s) with respect to indications and intended use.

Predicate Device Comparison Table Differences		
Item	***H. PYLORI CHEK*™**	**Premier® Platinum HpSA® PLUS (K053335)**
Specimen Type	Fresh or frozen formed, semi-solid, and liquid fecal specimens. Fecal specimens in Cary-Blair and C&S Transport Media	Fresh or frozen formed, semi-solid, and liquid fecal specimens
Specimen Storage	Specimens may be held up to 96 hours at 2°C – 8°C or at 20°C – 25°C prior to testing	Specimens may be held up to 72 hours at 2°C – 8°C prior to testing
Incubation Temp	37°C ± 2°C	19°C – 27°C
Time to Result	Approximately 1 hour	Approximately 1 hour
Antibody Format	Polyclonal/Polyclonal	Monoclonal/Monoclonal

Summary of Performance Data

The performance of the *H. PYLORI CHEK*™ test was evaluated at 6 independent sites. Patients were recruited that were undergoing endoscopy as part of routine care. A composite reference method (CRM) comparison was used in the evaluation consisting of rapid urease and histology of the biopsy samples. The following table shows a summary of the clinical performance data. The results of the study show that the *H. PYLORI CHEK*™ test by dual wavelength spectrophotometric analysis, exhibited sensitivity of 100% and specificity of 96.1% with CRM biopsy results. Testing was also conducted by visual reading of plates. Visual results were the same as dual wavelength spectrophotometric results 99% of the time.

Age and Gender Distribution

Age information was available (from the prospective study Initial Diagnosis group) for 109 patients. The ages ranged from 19 to 82 years. The gender identification was available for 109 patients. Of the 109 patients tested, 66% were female and 34% were male. No difference in test performance was observed based on patient age or gender.

Initial Diagnosis *H. PYLORI CHEK*™ test versus Composite reference Method (CRM)

N = 109	CRM Positive	CRM Negative
***H. PYLORI CHEK*™ Positive**	**32**	**3***
***H. PYLORI CHEK*™ Negative**	**0**	**74**

		95% Confidence Limits
Sensitivity	100%	89.3% - 98.9%
Specificity	96.1%	89.2% - 98.7%

*All three specimens tested positive initially by the *H. PYLORI CHEK*™ test, but negative upon re-testing with the *H. PYLORI CHEK*™ test.

Post-Therapy

For Eradication (post-therapy), there were 9 samples from patients being tested post therapy. The results show that the *H. PYLORI CHEK*™ test exhibited a sensitivity of 77.8% with the composite reference method.

N = 9	CRM Positive	CRM Negative
***H. PYLORI CHEK*™ Positive**	**7***	**0**
***H. PYLORI CHEK*™ Negative**	**2****	**0**

		95% Confidence Limits
Sensitivity	77.8%	45.3% - 93.7%

*One specimen tested positive by visual read but negative by spectrophotometric interpretation ($OD_{450/620}$ 0.034).

**One specimen tested negative initially but positive upon re-testing with the *H. PYLORI CHEK*™ test.

Retrospective Sample Study

A supplemental retrospective sample study was performed comparing the *H. PYLORI CHEK*™ test to an FDA cleared commercial ELISA. For this study, 196 samples (75 positive and 121 negative by the commercial ELISA) were evaluated. There was 100% correlation of results between the assays.

N = 196	FDA Cleared Commercial ELISA Positive	FDA Cleared Commercial ELISA Negative
***H. PYLORI CHEK*™ Positive**	**75**	**0**
***H. PYLORI CHEK*™ Negative**	**0**	**121**

		95% Confidence Limits
Percent Positive Agreement	100.0%	95.1% - 100.0%
Percent Negative Agreement	100.0%	96.9% – 100.0%

Reproducibility

The reproducibility of the *H. PYLORI CHEK*™ test was determined using 8 fecal specimens that were coded to prevent identification during testing. Testing was performed at 2 independent laboratories and on-site at TECHLAB, Inc. The samples were tested in triplicate twice a day over a 5-day period by multiple technicians at each site using 2 different kit lots. The results were consistent among the different locations and exhibited a correlation of 97.5%.

Analytical Specificity (Cross Reactivity)

The *H. PYLORI CHEK*™ test was evaluated for cross-reactivity with common intestinal organisms and viruses listed below. None of the organisms or viruses were shown to interfere with the performance of the *H. PYLORI CHEK*™ test.

Acinetobacter baumannii	*Bacillus cereus*	*Bacillus subtilis*
Borrelia burgdorferi	*Campylobacter coli*	*Campylobacter fetus*
Campylobacter helveticus	*Campylobacter hyointestinalis*	*Campylobacter jejuni*
Campylobacter lari	*Campylobacter upsaliensis*	*Candida albicans*
Clostridium bifermentans	*Clostridium difficile*	*Clostridium perfringens*
Edwardsiella tarda	*Enterobacter cloacae*	*Enterococcus faecalis*
Escherichia coli	*Escherichia coli EIEC*	*Escherichia coli EPEC*
Escherichia coli ETEC	*Escherichia coli* O157:H7 (non-toxigenic)	
Escherichia coli O157:H7 (toxigenic)	*Haemophilus influenzae*	*Lactobacillus acidophilus*
Listeria monocytogenes	*Peptostreptococcus anaerobius*	*Porphyromonas asaccharolytica*
Prevotella melaninogenica	*Proteus vulgaris*	*Pseudomonas aeruginosa*
Pseudomonas fluorescens	*Salmonella typhimurium*	*Staphylococcus aureus*
Staphylococcus aureus (Cowan's)	*Streptococcus agalactiae*	*Yersinia enterocolitica*

Adenovirus Types 2, 40	Human Coronavirus	Coxsackievirus B1, B2, B3, B6
Echovirus 9, 22	Enterovirus 70	Human Rotavirus

Inclusivity Study

The following strains, which include isolates representing described *H. pylori* populations, were tested for reactivity with the *H. PYLORI CHEK*™ test. All strains tested generated a positive result.

ATCC 700392	ATCC 43526	ATCC 700824
JP26	ATCC 43504	ATCC 43579

Interfering Substances (U.S. Formulation)

The following substances had no effect on positive or negative *H. PYLORI CHEK*™ test results analyzed at the concentrations indicated:
Barium sulfate (5% w/v), Benzalkonium Chloride (1% w/v), Ciprofloxacin (0.25% w/v), Ethanol (1% w/v), Hog gastric mucin (3.5% w/v), Human blood (40% v/v), Hydrocortisone (1% w/v), Imodium® (5% v/v), Kaopectate® (5% v/v), Leukocytes (0.05% v/v), Maalox® Advanced (5% v/v), Mesalazine (10% w/v), Metronidazole (0.25% w/v), MiraLax® (3350 PEG)(7% w/v), Mineral Oil (10% w/v), Mylanta® (4.2 mg/mL), Naproxen Sodium (5% w/v), Nonoxynol-9 (1% w/v), Nystatin (1% w/v), Palmitic Acid/Fecal Fat (40% w/v), Pepto-Bismol® (5% v/v), Phenylephrine (1% w/v), Prilosec OTC® (5 µg/mL), Sennosides (1% w/v), Simethicone (10% w/v), Stearic Acid/Fecal Fat (40% w/v), Tagamet® (5 µg/mL), TUMS® (50 µg/mL), Human Urine (5% v/v), and Vancomycin (0.25% w/v).

Analytical Sensitivity

The Limit of Detection (LoD) for the *H. PYLORI CHEK*™ test was established at 6.70 ng/mL in fecal matrix (0.13 ng/test) for *Helicobacter pylori* antigen using cell lysate antigen prepared from *H. pylori* strain ATCC 43526. For specimens in Cary Blair media, the LoD was established at 26.57 ng/mL (0.33 ng/test). For specimens in C&S media, the LoD was established at 18.19 ng/mL (0.23 ng/test).

Precision – Intra-Assay

For the determination of intra-assay performance, 8 fecal samples were analyzed by the *H. PYLORI CHEK*™ test. The samples included 2 negative, 2 high negative, 2 low positive, and 2 moderate positive samples. Each specimen was assayed a total of five times using two different kit lots. Positive specimens tested as expected and negative specimens consistently tested negative.

Precision – Inter-Assay

For the determination of inter-assay performance, 8 fecal samples were analyzed by the *H. PYLORI CHEK*™ test. The samples included 2 negative, 2 high negative, 2 low positive, and 2 moderate positive samples. The samples were tested twice a day by multiple technicians over a 12-day period using 2 different kit lots. The positive samples tested as expected 98.3% of the time and the negatives tested as expected 97.8% of the time.

Fresh Versus Frozen Samples

The effect of long term frozen specimen storage on antigen stability was evaluated. For the analysis, a total of 32 fecal specimens was tested with the *H. PYLORI CHEK*™ test. The fecal specimens consisted of 2 negative fecal samples, 5 high negative fecal samples, 10 low positive fecal samples, and 15 positive fecal samples covering the range of the test (50 ng/mL – 1200 ng/mL). Samples were prepared and stored ≤ -10°C and ≤ -70°C and tested at 0, 5, 10, and 14 days. No conversion of positive-to-negative or negative-to-positive was observed in any of the samples at the specified time points.

Prozone

To ensure that a high concentration of *H. pylori* antigen does not interfere with a positive reaction in the *H. PYLORI CHEK*™ test, high positive samples were prepared by spiking a negative fecal pool at concentrations up to 10 times the highest concentration of antigen observed in a positive clinical specimen. A total of 5 different dilutions of *H. pylori* antigen was prepared and tested in triplicate. The results demonstrated that there was no overall prozone effect, that elevated levels of antigen did not affect the detection of the antigen.

Conclusion

The conclusions drawn from the nonclinical and clinical tests demonstrate that the *H. PYLORI CHEK*™ test is safe and effective and substantially equivalent to the predicate device in performance. The information submitted in this premarket notification is complete and supports a substantial equivalence decision.