August 21, 2018

TECHLAB, Inc.
Donna Link
Director Regulatory and Compliance
2001 Kraft Drive
Corporate Research Center
Blacksburg, Virginia 24060-6358

Re: K181379
Trade/Device Name: H. Pylori Quik Chek
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter fetus serological reagents
Regulatory Class: Class I
Product Code: LYR
Dated: May 23, 2018
Received: May 24, 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 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,

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)*
K181379

Device Name
H. PYLORI QUIK CHEK

Indications for Use *(Describe)*

The TECHLAB H. PYLORI QUIK CHEK™ test is a rapid membrane enzyme immunoassay for the qualitative detection of Helicobacter pylori specific antigen in a single use cassette. 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 QUIK 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 16, 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 QUIK 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 rapid membrane enzyme immunoassay for the qualitative detection of *H. pylori* in a single use cassette.

Intended Use

The TECHLAB® *H. PYLORI QUIK CHEK*™ test is a rapid membrane enzyme immunoassay for the qualitative detection of *Helicobacter pylori* specific antigen in a single use cassette. 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.

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician

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 QUIK CHEK*™ test allows for the non-invasive detection of *H. pylori* when endoscopy is not required.

Device Description

The *H. PYLORI QUIK CHEK*™ test utilizes antibodies specific for *H. pylori* antigen. The *Membrane Device* contains a *Reaction Window* with two vertical lines of immobilized antibodies. The test line ("T") contains antibodies specific for *H. pylori* antigen. The control line ("C") contains antibodies to horseradish peroxidase (HRP). The *Conjugate* consists of antibodies to *H. pylori* antigen coupled to horseradish peroxidase. To perform the test, the sample is added to a tube containing a mixture of *Diluent* and *Conjugate*. The diluted sample-conjugate mixture is added to the *Sample Well* and the device is allowed to incubate at room temperature for 15 minutes. During the incubation, any *H. pylori* antigen in the sample binds to the antibody-peroxidase conjugate. The antigen-antibody-peroxidase complexes migrate through a filter pad to a membrane where they are captured by the immobilized anti-*H. pylori* antigen antibodies in the test line. The *Reaction Window* is subsequently washed with *Wash Buffer*, followed by the addition of *Substrate*. After a 10-minute incubation period, the *Reaction Window* is examined visually for the appearance of vertical blue lines on the "C" and "T" sides of the *Reaction Window.* A blue line on the "T" side of the *Reaction Window* indicates a positive result. A positive "C" reaction, indicated by a vertical blue line on the "C" side of the *Reaction Window*, confirms that the sample and reagents were added correctly, the reagents were active at the time of performing the assay, and that the sample migrated properly through the *Membrane Device*. It also confirms the reactivity of the other reagents associated with the assay.

Materials Provided

- ***Membrane Devices*** *- 25 pouches, each pouch contains 1 device*
- ***Conjugate (2.5 mL)*** *– Antibody specific for H. pylori antigen coupled to horseradish peroxidase in a buffered protein solution*
- ***Diluent (22 mL)*** *– Buffered protein solution with black graduated dropper assembly*
- ***Positive Control (2 mL)*** *– H. pylori antigen in a buffered protein solution*
- ***Substrate (3.5 mL)*** *- Solution containing tetramethylbenzidine*
- ***Wash Buffer (12 mL)*** *– Buffered solution with white graduated dropper assembly*
- ***Disposable plastic pipettes (50)*** *- Graduated at 25 µL, 100 µL, 200 µL, 300 µL, 400 µL and 500 µL*
- ***Wooden applicator sticks (50)***

The predicate device (Immuno*Card* STAT!® HpSA) and the *H. PYLORI QUIK CHEK*™ test both detect *H. pylori* in fecal specimens and are substantially equivalent in principle. The following table shows a comparison of both devices.

Predicate Device Comparison Table Similarities		
Item	***H. PYLORI QUIK CHEK*™**	**Immuno*Card* STAT!® HpSA (K032222)**
Intended Use	The TECHLAB® *H. PYLORI QUIK CHEK*™ test is a rapid membrane enzyme immunoassay for the qualitative detection of *Helicobacter pylori* specific antigen in a single use cassette. 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.	Immuno*Card* STAT! HpSA is a rapid in vitro qualitative assay for the detection of *Helicobacter pylori* antigen in human stool. The stool antigen detection is intended to aid in the diagnosis of *H. pylori* infection and to demonstrate loss of *H. pylori* stool antigen following treatment. Conventional medical practice recommends that testing by any method to confirm the loss of antigen be done at least four weeks following completion of therapy.
Measured analyte	Detection of *H. pylori* stool antigen	Detection of *H. pylori* stool antigen
Target Population	Persons suspected of having *H. pylori* infection	Same
Type of Test	Qualitative	Same

Predicate Device Comparison Table Similarities (continued)		
Item	***H. PYLORI QUIK CHEK*™**	**Immuno*Card* STAT!® HpSA (K032222)**
Controls	Positive and negative control included in kit Internal Control line	Same
Storage	Refrigerated (2°C – 8°C)	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 QUIK CHEK*™**	**Immuno*Card* STAT!® HpSA (K032222)**
Format	Single Use Membrane Cassette 25 tests	Single Use Lateral Flow Cassette 20 tests
Specimen Type	Fecal Specimens in Cary-Blair and C&S Transport Media	Unpreserved Fecal Specimen
Time to Result	30 minutes	5 minutes
Technology	Enzyme Linked Immunoassay (ELISA)	Immunochromatographic (ICT)
Antibody Format	Polyclonal/Polyclonal	Monoclonal/Monoclonal

Summary of Performance Data

The performance of the *H. PYLORI QUIK 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 QUIK CHEK*™ test exhibited sensitivity of 97.0% and specificity 100% with CRM biopsy results.

Age and Gender Distribution

Age and gender information was available for 122 patients. The ages ranged from 19 to 82 years. Of the 122 patients tested, 68% were female and 32% were male. No difference in test performance was observed based on patient age or gender.

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

N = 122	CRM Positive	CRM Negative
***H. PYLORI QUIK CHEK*™ Positive**	**32**	**0**
***H. PYLORI QUIK CHEK*™ Negative**	**1***	**89**

		95% Confidence Limits
Sensitivity	97.0%	84.7% - 99.5%
Specificity	100.0%	95.9% - 100.0%

*Additional testing with an FDA cleared *H. pylori* stool antigen teste provided an antigen negative result.

Post-Therapy

For Eradication (post-therapy), there were 9 samples from patients being tested post therapy. The results show that the *H. PYLORI QUIK CHEK*™ test exhibited a sensitivity of 100% with the composite reference method.

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

		95% Confidence Limits
Sensitivity	100.0%	70.1% - 100.0%

Retrospective Sample Study

A supplemental retrospective sample study was performed comparing the *H. PYLORI QUIK CHEK*™ test to an FDA cleared commercial ELISA. For this study, 200 samples (94 positive and 106 negative by the commercial ELISA). There was 98.9% Positive Agreement and 97.2% Negative Agreement of results between the assays.

N = 200	FDA Cleared Commercial ELISA Positive	FDA Cleared Commercial ELISA Negative
***H. PYLORI QUIK CHEK*™ Positive**	**93**	**3***
***H. PYLORI QUIK CHEK*™ Negative**	**1****	**103**

		95% Confidence Limits
Percent Positive Agreement	98.9%	94.2% - 99.8%
Percent Negative Agreement	97.2%	92.0% – 99.0%

**H. pylori* DNA was amplified from the samples with PCR
**No *H. pylori* DNA was amplified from the sample with PCR

Reproducibility

The reproducibility of the *H. PYLORI QUIK 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 as expected among the different locations, and exhibited an overall percent agreement of 100%.

Analytical Sensitivity

The Limit of Detection (LoD) for the *H. PYLORI QUIK CHEK*™ test was established at 16.08 ng/mL in fecal matrix (0.24 ng/test) for *Helicobacter pylori* antigen using cell lysate antigen prepared from *H. pylori* strain ATCC 43526. For specimens in Protocol™ Cary Blair media, the LoD was established at 13.01 ng/mL (0.20 ng/test). For specimens in Protocol™ C&S media, the LoD was established at 19.96 ng/mL (0.31 ng/test).

Analytical Specificity (Cross Reactivity)

The *H. PYLORI QUIK 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 QUIK 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 QUIK 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 QUIK 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).

Prozone

To ensure that a high concentration of *H. pylori* antigen does not interfere with a positive reaction in the *H. PYLORI QUIK 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 QUIK 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.