DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

ALERE SAN DIEGO, INCORPORATED
JOSEPH DE LA ROSA
RA SPECIALIST
9975 SUMMERS RIDGE ROAD
SAN DIEGO CA 92121

August 12, 2015

Re: K151935
Trade/Device Name: Alere Signify *H. pylori* Whole Blood, Serum, Plasma
Alere Signify *H. pylori* Whole Blood Only
Alere Clearview *H. pylori* Whole Blood, Serum, Plasma
Alere Clearview *H. pylori* Whole Blood Only
Regulation Number: 21 CFR 866.3110
Regulation Name: *Campylobacter fetus* serological reagents
Regulatory Class: I
Product Code: LYR
Dated: July 13, 2015
Received: July 14, 2015

Dear Mr. De La Rosa:

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. 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151935

Device Name
Alere Signify® H. pylori – Whole Blood, Serum, Plasma; Alere Signify® H. pylori – Whole Blood Only;
Alere Clearview® H. pylori – Whole Blood, Serum, Plasma; Alere Clearview® H. pylori – Whole Blood Only

Indications for Use *(Describe)*
The Signify® H. pylori cassette is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to Helicobacter pylori in whole blood, serum or plasma to aid in the diagnosis of H. pylori infection in adults 18 years of age and older.

The Signify® H. pylori cassette is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to Helicobacter pylori in whole blood to aid in the diagnosis of H. pylori infection in adults 18 years of age and older.

The Clearview® H. pylori test is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to Helicobacter pylori in whole blood, serum or plasma to aid in the diagnosis of H. pylori infection in adults 18 years of age and older.

The Clearview® H. pylori test is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to Helicobacter pylori in whole blood to aid in the diagnosis of H. pylori infection in adults 18 years of age and older.

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

GENERAL INFORMATION

Submitted By: Alere, Inc.
9975 Summers Ridge Road
San Diego, CA 92121
Establishment # 2027969

Company Contact: Joseph De La Rosa
Regulatory Affairs Specialist
858-805-3181
Joseph.delarosa@alere.com

Date Prepared: August 10, 2015

DEVICE IDENTIFICATION

Trade or Proprietary Names:	Alere Signify® *H. pylori* – Whole Blood, Serum, Plasma Alere Signify® *H. pylori* – Whole Blood Only Alere Clearview® *H. pylori* – Whole Blood, Serum, Plasma Alere Clearview® *H. pylori* – Whole Blood Only
Common Name:	Qualitative Immunoassay for *H. pylori*
Device Classification Name:	*Camplyobacter pylori*
Product Code:	LYR
Regulatory Class:	Class I (reserved)
Classification Regulation:	21 CFR 866.3110
Predicate Device:	Alere *H. pylori* Rapid Test Strip and Test Device

DEVICE DESCRIPTION

The Alere *H. pylori* tests are lateral flow immunochromatographic assays for the qualitative detection of Immunoglobulin G (IgG) antibodies to *Helicobacter pylori (H. pylori)* in whole blood, serum and plasma. The test devices consist of a membrane strip coated with immobilized human IgG antibodies and *H. pylori* antigen encased in a plastic housing. In the test procedure, anti-human IgG is immobilized in the test line region of the cassette. The sample reacts with *H. pylori* antigen-coated particles that have been applied to the label pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized anti-human IgG. If the sample contains *H. pylori* IgG antibodies, a colored line will appear in the test line region

indicating a positive result. If the sample does not contain *H. pylori* IgG antibodies, a colored line will not appear in this region indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of sample has been added and membrane wicking has occurred.

Intended Use

The Alere *H. pylori* Immunoassay intended use statements are as follows:

Product Name	Intended Use
Alere Signify® *H. pylori* – Whole Blood, Serum, Plasma	The Signify® *H. pylori* cassette is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to Helicobacter pylori in whole blood, serum or plasma to aid in the diagnosis of *H. pylori* infection in adults 18 years of age and older.
Alere Signify® *H. pylori* – Whole Blood Only	The Signify® *H. pylori* cassette (Whole Blood) is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to Helicobacter pylori in whole blood to aid in the diagnosis of *H. pylori* infection in adults 18 years of age and older.
Alere Clearview® *H. pylori* – Whole Blood, Serum, Plasma	The Clearview® *H. pylori* test is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to Helicobacter pylori in whole blood, serum or plasma to aid in the diagnosis of *H. pylori* infection in adults 18 years of age and older.
Alere Clearview® *H. pylori* – Whole Blood Only	The Clearview® *H. pylori* test is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to Helicobacter pylori in whole blood to aid in the diagnosis of H. pylori infection in adults 18 years of age and older.

COMPARISON WITH PREDICATE

Attribute	Alere *H. pylori* Immunoassays	ACON *H. pylori* Rapid Test Strip and Test Device (k024350)
Similarities		
Intended Use	The Alere H. pylori cassette is a rapid chromatographic immunoassay for the qualitative detection of IgG antibodies to Helicobacter pylori in whole blood, serum or plasma to aid in the diagnosis of *H. pylori* infection in adults 18 years of age and older.	Same
Format	Qualitative lateral flow antigen/antibody immunoassay	Same
Sample	Whole blood, serum, plasma	Same
Minimum sample volume	Approximately 50 µL	Same
Analyte	IgG antibodies specific to *Helicobacter pylori* in human blood, serum or plasma	Same
Quality control	Control region bound to test strip. Red line in control region indicates valid sample application. Positive and negative control sample included in kit.	Same
Test Time	10 minutes	Same
Endpoint	Colored lines	Same
Differences		
Interfering substances	No interference with the H. pylori test results was observed in samples containing high levels of hemoglobin (up to 1,000 mg/dL), bilirubin (up to 1,000 mg/dL) and human serum albumin (up to 2,000 mg/mL) and triglycerides (up to 3454 mg/dL). The test results were also unaffected when the hematocrit was altered ranging from 20% to 67%.	No interference with *ACON H. Pylori* Rapid Test Device (Whole Blood/Serum/Plasma results was observed in samples containing high levels of hemoglobin (up to 1000 mg/dL), bilirubin (up to 1000 mg/dL) and human serum albumin (up to 2000 mg/mL). The test results were also unaffected when the hematocrit was altered ranging from 20% to 67%.

PERFORMANCE DATA

An interfering substance study was conducted to determine the performance of the *H. pylori* tests when testing samples with increased levels of triglycerides. Separate tests were conducted for plasma, serum and whole blood samples.

H. pylori standards – low positive, positive and high positive – plus an *H. pylori* negative plasma sample were spiked each with two concentrations of triglyceride reference material (797 mg/dL and 3454 mg/dL) and tested in replicates of three per sample. Three unspiked replicates of each of the *H. pylori* standards and negative were also tested. All negative and positive *H. pylori* samples tested as expected with no false results due to the presence of high levels of triglycerides in the samples.

CONCLUSIONS

The differences indicated between the modified labeling for the device and the predicate do not constitute a new intended use. There are no changes to the safety and effectiveness of the device and the impact on clinical management and patient health. Therefore the device with modified labeling is considered substantially equivalent to the predicate.