August 31, 2018

DiaSorin Inc.
Sandra Zimniewicz
Regulatory Affairs Specialist
1951 Northwestern Ave.
Stillwater, Minnesota 55082-0285

Re: K181464
Trade/Device Name: LIAISON Helicobacter Antigen, LIAISON Helicobacter Antigen Control Set
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter fetus serological reagents
Regulatory Class: Class I
Product Code: LYR, JJX, JJF
Dated: June 5, 2018
Received: June 6, 2018

Dear Sandra Zimniewicz:

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)*
K181464

Device Name
LIAISON® Helicobacter Antigen
LIAISON® Helicobacter Antigen Control Set

Indications for Use *(Describe)*
The LIAISON® Helicobacter Antigen assay is a chemiluminescent immunoassay (CLIA) intended for the qualitative determination of Helicobacter pylori (H. pylori) antigen in human stool. The test is an aid in the diagnosis of patients suspected of H. pylori infection and to measure post therapy response from patients who have discontinued therapy for at least 4 weeks. Assay results should be used in conjunction with other clinical and laboratory data to assist the clinician in making individual patient management decisions.
The test must be performed on the LIAISON® XL Analyzer.

The LIAISON® Helicobacter Antigen Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Helicobacter Antigen assay.
The performance characteristics of the LIAISON® Helicobacter Antigen Control Set have not been established for any other assay or instrument platforms different from the LIAISON® XL.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

SUBMITTED BY: Sandra Zimniewicz
Regulatory Affairs Specialist
DiaSorin Inc.
1951 Northwestern Avenue
P.O. Box 285
Stillwater, MN 55082-0285
Phone (651) 351-5711
Fax (651) 351-5711
Email: sandra.zimniewicz@diasorin.com

DATE PREPARED: August 31, 2018

NAME OF DEVICE:

Trade Name:	LIAISON® *Helicobacter* Antigen LIAISON® *Helicobacter* Antigen Control Set
Common Names/Descriptions:	*Helicobacter pylori* Antigen assay and *Helicobacter pylori* Antigen controls
Classification Names:	Campylobacter fetus serological reagents: Class l, 21 CFR: 866.3110; Microbiology (83) Single (Specified) analyte controls (assayed and unassayed): Class l, 21 CFR 862.1660; Clinical Chemistry (75)
Product Code:	LYR - Campylobacter fetus serological reagents JJX - Single (Specified) analyte controls (assayed and unassayed) JJF – Analyzer, Chemistry, Micro, For Clinical Use
PREDICATE DEVICES :	Meridian Platinum Premier HpSA PLUS Reference K053335 assay LIAISON® *H. pylori* IgG Control Set (K161139)

DEVICE DESCRIPTION:

INTENDED USE:

The LIAISON® *Helicobacter* Antigen assay is a chemiluminescent immunoassay (CLIA) intended for the qualitative determination of *Helicobacter pylori* (*H. pylori*) antigen in human stool. The test is an aid in the diagnosis of patients suspected of *H. pylori* infection and to measure post therapy response from patients who have discontinued therapy for at least 4 weeks. Assay results should be used in conjunction with other

clinical and laboratory data to assist the clinician in making individual patient management decisions.
The test must be performed on the LIAISON® XL Analyzer.

The LIAISON® *Helicobacter* Antigen Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® *Helicobacter* Antigen assay. The performance characteristics of the LIAISON® *Helicobacter* Antigen Control Set have not been established for any other assay or instrument platforms different from the LIAISON® XL.

KIT DESCRIPTION:

The LIAISON® *Helicobacter* Antigen assay is a delayed one-step sandwich assay for detection of *H. pylori* stool antigen. *H. pylori* antigen is first extracted from human stool samples with sample diluent using the LIAISON® Stool Extraction Device.

The assay uses a monoclonal antibody for detection of *H. pylori* stool antigen. The assay uses 200 µL of sample consisting of a mixture of extraction buffer and stool extracted *H. pylori* stool antigen which is incubated with paramagnetic particles coated with a capture antibody for *H. pylori* stool antigen. Following incubation, an isoluminol conjugated antibody for *H. pylori* stool antigen is added to the reaction and incubated. After the second incubation, the unbound material is removed with a wash cycle. The starter reagents are then added and a flash chemiluminescent reaction is initiated. The light signal is measured by a photomultiplier as relative light units (RLU) and is proportional to the concentration of H. pylori stool antigen present in the calibrators, controls or samples.

All assay steps and incubations are performed by the LIAISON® XL Analyzer.

COMPARISON TO FDA CLEARED METHOD

Similarities		
Item	**Device: LIAISON® *Helicobacter* Antigen (K181464)**	**Predicate: Premier Platinum HpSA PLUS (K053335)**
Product Code	LYR	Same
Intended Use	The LIAISON® Helicobacter Antigen assay is a chemiluminescent immunoassay (CLIA) intended for the qualitative determination of Helicobacter pylori (H. pylori) antigen in human stool. The test is an aid in the diagnosis of patients suspected of H. pylori infection and to measure post therapy response from patients who have discontinued therapy for at least 4 weeks. Assay results should be used in conjunction with other clinical and	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

Similarities		
Item	**Device: LIAISON® *Helicobacter* Antigen (K181464)**	**Predicate: Premier Platinum HpSA PLUS (K053335)**
	laboratory data to assist the clinician in making individual patient management decisions. The test must be performed on the LIAISON® XL Analyzer. The LIAISON® Helicobacter Antigen Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Helicobacter Antigen assay. The performance characteristics of the LIAISON® Helicobacter Antigen Control Set have not been established for any other assay or instrument platforms different from the LIAISON® XL.	patients. Accepted medical practice recommends that testing by any current method, to confirm eradication, be done at least four weeks following completion of therapy.
Results	Qualitative	Same
Measurand	*H. pylori* antigen	Same
Specimen Required	Stool	Same

Differences		
Item	**Device: LIAISON *Helicobacter* Antigen (K181464)**	**Predicate: Premier Platinum HpSA PLUS (K053335)**
Limit of Detection	4 ng/mL	≥ 4.67 ng/mL in stool
Technology	Automated Chemiluminescent Immunoassay (CLIA)	Manual/Semiautomated Enzyme Immunoassay (EIA)
Cutoff	1.1 Index (for positive)	0.100 at $OD_{450/630}$
Interpretation	Negative <0.90 Index Equivocal (≥ 0.90 Index and < 1.10 Index) Positive ≥ 1.10 Index	Negative <0.100 $OD_{450/630}$ Positive ≥ 0.100 $OD_{450/630}$

PERFORMANCE DATA:

COMPARATIVE CLINICAL STUDIES:

A prospective study was performed to compare the performance of the LIAISON®

Helicobacter Antigen assay to at least two of the three methods which comprise the Composite Reference Method (CRM): Histological Evaluation, Culture of the Organism, and Urease Detection Test.
The prospective study consisted of 285 specimens collected from subjects undergoing evaluation for *H. pylori* infection to determine infection status both pre and post therapy. Prospective samples were collected at multiple sites, and regions, within the US and outside the US (OUS).

Pre-Therapy population
The pre-therapy study population consisted of 277 male or female adult subjects (≥ 22 years), undergoing evaluation to determine *H. pylori* infection status prior to any therapeutic intervention.

The results are summarized as sensitivity and specificity with 95% confidence intervals.

H. pylori Pre-Therapy Population Comparison

LIAISON® *Helicobacter* Antigen	Composite Reference Method Diagnosis		
	Infected	Not Infected	Total
Positive	64	3	67
Equivocal	0	0	0
Negative	3	207	210
Total	67	210	277

			95% Confidence Interval
Clinical Specificity	207/210	98.6%	95.9 – 99.7%
Clinical Sensitivity	64/67	95.5%	87.5 – 99.1%

Post-Therapy population
The post-therapy study population consisted of 8 male or female adult subjects (≥ 22 years), undergoing evaluation to measure post therapy response for *H. Pylori*.

The results are summarized as sensitivity with 95% confidence intervals.

H. pylori Post-Therapy Population Comparison

LIAISON® *Helicobacter* Antigen	Composite Reference Method Diagnosis		
	Infected	Not Infected	Total
Positive	8	0	8
Equivocal	0	0	0
Negative	0	0	0
Total	8	0	8

			95% Confidence Interval
Clinical Sensitivity	8/8	100%	63.1 – 100 %

Prevalence:

The observed prevalence of the LIAISON® *Helicobacter* Antigen assay was calculated from the 277 specimens obtained from eligible subjects of the pre-therapy population who underwent EGD with signs and symptoms of a *Helicobacter* pylori infection. The specimens were from 86 males (31%) and 191 females (69%), collected from multiple U.S. and OUS geographical locations. Known ages ranged from 22 to 87 years old.

The observed prevalence of the LIAISON® *Helicobacter* Antigen assay is 24.2%. The prevalence may vary depending upon geographical location, age, gender, type of test employed, specimen collection and handling procedures as well as clinical history of the patient.

PRECISION/REPRODUCIBILITY:

12 Day Study

A within-laboratory precision study was performed consulting CLSI document EP5-A3 in the preparation of the testing protocol. Six contrived antigen samples containing high negative, low positive and moderate positive concentrations of *H. pylori* stool antigen and kit controls (negative and positive). All samples and controls were assayed in duplicate, two runs per day over twelve operating days with multiple technicians. The following within-laboratory precision results were obtained from samples tested internally at DiaSorin Inc. with one kit lot using one LIAISON® XL Analyzer.

Within-Laboratory Precision

Sample ID N=48	Mean Index	Within Run		Within Day		Between Day		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
Neg Ctrl	0.06	0.00	7.8%	0.00	0.0%	0.00	4.6%	0.00	7.8%
Neg Ctrl	0.06	0.00	7.6%	0.00	0.0%	0.00	5.6%	0.01	8.8%
Pos Ctrl	2.72	0.05	1.9%	0.04	1.5%	0.03	1.2%	0.07	2.6%
Pos Ctrl	2.70	0.06	2.4%	0.03	1.2%	0.01	0.2%	0.07	2.7%
Sample #1	0.80	0.02	2.6%	0.02	2.3%	0.03	3.1%	0.04	4.7%
Sample #2	0.84	0.02	2.9%	0.01	1.0%	0.03	3.8%	0.04	4.9%
Sample #3	1.84	0.06	3.1%	0.02	1.2%	0.04	2.4%	0.08	4.1%
Sample #4	1.99	0.04	2.1%	0.07	3.5%	0.02	1.0%	0.08	4.2%
Sample #5	3.03	0.08	2.7%	0.00	0.0%	0.07	2.2%	0.10	3.3%
Sample #6	3.00	0.08	2.6%	0.06	2.1%	0.06	2.0%	0.12	3.9%

5 Day Study

A reproducibility/precision study was performed at two external sites and internally at DiaSorin Inc. consulting CLSI document EP15-A3 in the preparation of the testing protocol. Six contrived antigen samples containing high negative, low positive and

moderate positive concentrations of *H. pylori* stool antigen and kit controls (negative and positive) as duplicate samples were assayed in replicates of three, in two runs per day over 5 operating days with two technicians at each site performing the test every day. The following reproducibility/precision results were obtained from samples tested at the three sites using one kit lot.

Reproducibility

Sample ID	Mean Index Value	Within Run		Run to Run Within Day		Day to Day Within Site		Site to Site		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Neg Ctrl	0.07	0.004	5.1%	0.002	2.4%	0.002	2.1%	0.009	12.5%	0.010	13.9%
Neg Ctrl	0.07	0.003	4.0%	0.003	4.0%	0.001	1.4%	0.007	10.0	0.009	11.5%
Pos Ctrl	4.80	0.076	1.6%	0.050	1.0%	0.063	1.3%	0.105	2.2%	0.153	3.1%
Pos Ctrl	4.78	0.070	1.5%	0.050	1.0%	0.068	1.4%	0.113	2.4%	0.157	3.3%
Sample #1	2.12	0.034	1.6%	0.038	1.8%	0.108	5.1%	0.119	5.6%	0.168	8.0%
Sample #2	2.37	0.049	2.1%	0.046	1.9%	0.156	6.6%	0.226	9.5%	0.283	11.9%
Sample #3	0.69	0.024	3.5%	0.021	3.0%	0.037	5.4%	0.065	9.4%	0.081	11.8%
Sample #4	0.69	0.023	3.3%	0.026	3.8%	0.019	2.7%	0.065	9.4%	0.077	11.0%
Sample #5	1.21	0.031	2.5%	0.037	3.1%	0.029	2.4%	0.093	7.7%	0.109	9.0%
Sample #6	1.20	0.021	1.7%	0.030	2.5%	0.056	4.7%	0.120	10.1%	0.138	11.5%

REAGENT STABILITY

LIAISON® *Helicobacter* Antigen	
Study	Stability
Calibration Curve	4 weeks
Reagent Integral Open Use storage On-board Analyzer	8 weeks
Reagent Integral Open Use storage at 2-8°C	8 weeks
Calibrator Freeze/Thaw cycles	3 cycles
Reconstituted Calibrator open use at room temperature (18-25°C)	8 hours
Reconstituted Calibrator open use at 2 - 8°C	28 days
Reconstituted Calibrator open use at -20°C	16 weeks

LIAISON® *Helicobacter* Antigen Control Set	
Study	Stability
Reconstituted Positive Control Open Use at -20°C	16 weeks
Reconstituted Positive Control Freeze/Thaw cycles	3 cycles
Negative and Reconstituted Positive Control Open Use storage at 2-8°C	28 days

SPECIMEN STABILITY

Studies were performed to determine the stability of sample at different storage conditions. The results are provided in the tables below.

Stool Sample	
Study	Stability
Refrigerated at 2- 8°C	72 hours
Store samples frozen at -20°C if not tested within 72 hours.	

Sample Extract	
Study	Stability
Room temperature (18 - 25°C)	8 hours
Refrigerated at 2- 8°C	72 hours
Frozen at -20°C	12 weeks
Freeze/Thaw cycles	3 cycles

CONCLUSION:

The material submitted in this premarket notification is complete and supports a substantial equivalence decision. The labeling is sufficient and it satisfies the requirements of 21CFR 809.10.