



July 22, 2016

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

DIASORIN, INC.
KELLY SAUCER
REGULATORY AFFAIRS SPECIALIST
1951 NORTHWESTERN AVE.
STILLWATER MN 55082-0285

Re: K161139

Trade/Device Name: Liaison H. pylori IgG, Liaison H. pylori IgG Control Set
Regulation Number: 21 CFR 866.3110
Regulation Name: Campylobacter fetus serological reagents
Regulatory Class: I
Product Code: LYR, JJX, JJQ
Dated: April 15, 2016
Received: April 22, 2016

Dear Ms. Saucer:

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,

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

Indications for Use

510(k) Number (if known)
K161139

Device Name
LIAISON® H. pylori IgG
LIAISON® H.pylori IgG Control Set

Indications for Use (Describe)

The LIAISON® H. pylori IgG assay uses chemiluminescent immunoassay (CLIA) technology for the qualitative determination of IgG antibodies to *Helicobacter pylori* in human serum from symptomatic adults as an aid in the diagnosis of *Helicobacter pylori* infection. Assay results should be used in conjunction with other clinical or laboratory data to assist the clinician in making individual patient management decisions. The test has to be performed on the LIAISON® XL Analyzer.

The LIAISON® H. pylori IgG Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® H. pylori IgG assay.

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.

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5.0 510(k) SUMMARY

SUBMITTED BY:

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DATE PREPARED:

April 15, 2016

NAME OF DEVICE:

Trade Name:

LIAISON® *H. pylori* IgG
LIAISON® *H. pylori* IgG Control Set

Common Names/Descriptions:

Helicobacter pylori IgG assay and
Helicobacter pylori IgG controls

Classification Names:

Campylobacter fetus serological reagents:
Class I, 21 CFR: 866.3110; Microbiology (83)

Product Code:

LYR - Campylobacter fetus serological reagents
JJX - Single (Specified) analyte controls
(assayed and unassayed)
JJQ - Colorimeter, photometer,
spectrophotometer for clinical use

PREDICATE DEVICES :

IMMULITE® 2000 *H. pylori* IgG
Reference K000463 (assay)
DiaSorin LIAISON® Control Toxo IgG II
(K132234)

DEVICE DESCRIPTION:

INTENDED USE:

The LIAISON® *H. pylori* IgG assay uses chemiluminescent immunoassay (CLIA) technology for the qualitative determination of IgG antibodies to *Helicobacter pylori* in human serum from symptomatic adults as an aid in the diagnosis of *Helicobacter pylori* infection. Assay results should be used in conjunction with other clinical or laboratory data to assist the clinician in making individual patient management decisions. The test has to be performed on the LIAISON® XL Analyzer.

The LIAISON® *H. pylori* IgG Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® *H. pylori* IgG assay.

KIT DESCRIPTION:

The method for qualitative determination of IgG antibodies to *Helicobacter pylori* (*H.pylori* IgG) is a two-step, indirect chemiluminescence immunoassay (CLIA). The principal components of the test are magnetic particles (solid phase) coated with *Helicobacter pylori* antigen and a conjugate of anti-human IgG monoclonal antibodies to linked to an isoluminol derivative (isoluminol-antibody conjugate). During the first incubation, *H. pylori* antibodies present in calibrators, samples or controls bind to the solid phase. During the second incubation, the monoclonal antibody conjugate reacts with *H. pylori* IgG that is already bound to the solid phase. After each incubation, unbound material is removed with a wash cycle.

Subsequently, the starter reagents are added and a flash chemiluminescence reaction is thus induced. The light signal, and therefore, the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) and is indicative of the presence of *H. pylori* IgG in calibrators, samples or controls.

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

COMPARISON TO PREDICATE DEVICE:

The DiaSorin LIAISON® *H. pylori* IgG assay is substantially equivalent in principle and performance to Siemens IMMULITE 2000 *H. pylori* IgG Assay (K000463) which was FDA cleared June 1, 2000.

Table 1: Table of Similarities		
Item	Device K161139	Predicate K000463
Intended Use	<p>The LIAISON® <i>H. pylori</i> IgG assay uses chemiluminescent immunoassay (CLIA) technology for the qualitative determination of IgG antibodies to <i>Helicobacter pylori</i> in human serum from symptomatic adults as an aid in the diagnosis of <i>Helicobacter pylori</i> infection. Assay results should be used in conjunction with other clinical or laboratory data to assist the clinician in making individual patient management decisions. The test has to be performed on the LIAISON® XL Analyzer.</p> <p>The LIAISON® <i>H. pylori</i> IgG Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® <i>H. pylori</i> IgG assay.</p>	<p>For <i>in vitro</i> diagnostic use with the IMMULITE® 2000 Systems Analyzers – for the qualitative detection of IgG antibodies to <i>Helicobacter pylori</i> in human serum from symptomatic adults, as an aid in the diagnosis of <i>Helicobacter pylori</i> infection</p>
Measured Analyte	IgG antibodies to <i>H. pylori</i>	Same

Table 1: Table of Similarities		
Item	Device K161139	Predicate K000463
Assay Type	Solid Phase Two Step Chemiluminescent	Same
Sample Handling	Automated	Same
Reagent Storage	On-board or in refrigerator @ 2-8°C	In refrigerator @ 2-8°C
Calibration	Two point verification of stored master curve	Same
Calibration Calculation of Result	Qualitative assay	Same
Sample Matrix	Human Serum	Same
Sample Size Volume	10 µL	Same
Controls	Provided separately	Same

Table 2 : Table of Differences		
Item	Device K161139	Predicate K000463
Unit of Measure	Index	U/mL
Assay Time	30 minutes	60 minutes
Conjugate	Mouse monoclonal antibodies to human IgG linked to an isoluminol derivative	Monoclonal murine anti-human IgG antibodies labeled with alkaline phosphatase in buffer
Measurement System	Photomultiplier (flash chemiluminescence reader)	Luminometer
Cutoff	0.85 Index	1.00 U/mL
Equivocal Zone	0.80 – < 0.90 Index	0.90 – < 1.10 U/mL
Controls	2 levels: negative and positive	3 levels: negative, low positive, positive
Control Stability Open Use	12 weeks	2 weeks
Calibration Stability	4 weeks	1 week

PERFORMANCE DATA:**COMPARATIVE CLINICAL STUDIES:**

A prospective study was performed to compare the performance of the LIAISON® *H. pylori* IgG assay to an FDA-cleared predicate device.

The prospective study consisted of 504 samples collected from non-selected adult subjects sent to the laboratory for *H. pylori* IgG serological testing.

A. Prospective:

The prospective population consisted of 504 adult subjects (Table 3) and collected from multiple locations geographical locations in the U.S.

The results are summarized as negative and positive percent agreement with 95% confidence intervals.

Table 3: *H. pylori* IgG Prospective Population Comparison

LIAISON® <i>H. pylori</i> IgG	Comparator Assay			Total
	Positive	Equivocal	Negative	
Positive	105	7	1	113
Equivocal	1	2	2	5
Negative	4	4	378	386
Total	110	13	381	504

		Percent Agreement	95% Confidence Interval
Negative	378/381	99.2%	97.9 – 99.8%
Positive	105/110	95.5%	90.4 – 98.4%

D. Prevalence:

The observed prevalence of the LIAISON® *H. pylori* IgG assay was calculated from the 504 samples collected from adult subjects sent to the lab for *H. pylori* IgG testing. The samples were from 151 males (30%) and 353 females (70%), and collected from multiple U.S. geographical locations. Known ages ranged from 18 to 91 years.

The observed prevalence of the LIAISON® *H. pylori* IgG is 22.4%. However, 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 serum samples containing high negative, low positive and moderate positive concentrations of *H. pylori* IgG and kit controls (negative and positive) as duplicate samples were assayed in duplicate, in two runs per day over 12 operating days with multiple technicians. The following within-laboratory precision results (Table 4) were obtained from samples tested internally at DiaSorin Inc. in one kit lot using one LIAISON® XL Analyzer.

Table 4. Within-Laboratory Precision

Sample ID	Mean Index	Within Run		Within Day		Between Day		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
Neg Ctrl	1341*	115	8.6%	46.8	3.5%	145	10.8%	190	14.2%
Neg Ctrl	1320*	120	9.1%	52.6	4.0%	119	9.0%	177	13.4%
Pos Ctrl	2.77	0.145	5.2%	0.119	4.3%	0.112	4.1%	0.218	7.9%
Pos Ctrl	2.73	0.144	5.3%	0.176	6.5%	0.053	1.9%	0.234	8.6%
Sample #1	0.74	0.049	6.6%	0.043	5.7%	0.051	6.8%	0.082	11.1%
Sample #2	0.71	0.048	6.7%	0.000	0.0%	0.030	4.2%	0.055	7.7%
Sample #3	1.32	0.071	5.4%	0.040	3.1%	0.075	5.7%	0.111	8.4%
Sample #4	1.25	0.081	6.5%	0.015	1.2%	0.053	4.3%	0.098	7.9%
Sample #5	1.52	0.076	5.0%	0.074	4.9%	0.000	0.0%	0.106	7.0%
Sample #6	1.50	0.084	5.6%	0.042	2.8%	0.095	6.3%	0.133	8.9%

Sample N=48

*Precision calculations are based on signal (RLU) for the two negative controls

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 serum samples containing high negative, low positive and moderate positive concentrations of *H. pylori* IgG 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 (Table 5) were obtained from samples tested at the three sites in one kit lot.

Table 5. Reproducibility

Sample ID	Mean Index	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	1013*	54.0	5.3%	25.4	2.5%	19.1	1.9%	50.4	5.0%	80.4	7.9%
Neg Ctrl	996*	43.7	4.4%	25.4	2.6%	0.900	0.1%	79.8	8.0%	94.5	9.5%
Pos Ctrl	3.34	0.111	3.3%	0.060	1.8%	0.013	0.4%	0.062	1.9%	0.141	4.2%
Pos Ctrl	3.36	0.103	3.1%	0.012	0.4%	0.068	2.0%	0.019	0.6%	0.126	3.7%
Sample #1	0.626	0.035	5.6%	0.010	1.6%	0.016	2.5%	0.061	9.8%	0.073	11.7%
Sample #2	0.628	0.025	4.0%	0.018	2.9%	0.005	0.7%	0.047	7.4%	0.056	9.0%
Sample #3	1.28	0.043	3.4%	0.004	0.3%	0.030	2.4%	0.064	5.0%	0.083	6.5%
Sample #4	1.27	0.050	3.9%	0.011	0.9%	0.035	2.7%	0.044	3.5%	0.076	6.0%
Sample #5	1.82	0.061	3.3%	0.049	2.7%	0.045	2.5%	0.067	3.7%	0.113	6.2%
Sample #6	1.74	0.060	3.4%	0.034	1.9%	0.041	2.4%	0.067	3.8%	0.104	6.0%

Sample N=90

*Precision calculations are based on signal (RLU) for the two negative controls

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.