K062473

APR 12 2007

5.0 510(k) SUMMARY

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name:	DiaSorin LIAISON® *Borrelia burgdorferi* DiaSorin LIAISON® *Borrelia burgdorferi* Serum Controls
Common Names/Descriptions:	*Borrelia burgdorferi* IgG/IgM
Classification Names:	Reagent, *Borrelia* Serological Reagent
Product Code:	LSR

PREDICATE DEVICES: Immunetics® C6 *B. burgdorferi* (Lyme) ELISA™ Kit - (K003754)

DEVICE DESCRIPTION:

INTENDED USE: The LIAISON® *Borrelia burgdorferi* assay and the LIAISON® *Borrelia burgdorferi* Serum Controls, use chemiluminescent immunoassay (CLIA) technology for the qualitative presumptive detection of IgG and IgM antibodies to *Borrelia burgdorferi* in human serum. This assay should be used only on samples from patients with signs and symptoms that are consistent with Lyme Disease. Positive or equivocal results should be supplemented by testing with a standardized Western Blot procedure. Positive supplemental results provide evidence of exposure to *Borrelia burgdorferi* and can be used to support a clinical diagnosis of Lyme Disease. Negative results by LIAISON® *Borrelia burgdorferi* assay should not be used to exclude Lyme Disease.

KIT DESCRIPTION: The method for the qualitative determination of IgG and IgM antibodies to *Borrelia burgdorferi* is an indirect chemiluminescence immunoassay (CLIA). All assay steps and incubations are performed by the LIAISON® Analyzer, with the exception of the initial magnetic particle resuspension.

Recombinant antigens specific for *Borrelia* (VlsE antigens) are used for coating the magnetic particles (solid phase). Two mouse monoclonal antibodies (anti-human IgG and anti-human IgM) are linked to an isoluminol derivative (isoluminol-antibody conjugate).

During the first incubation, anti-*Borrelia burgdorferi* antibodies present in calibrators, samples or controls bind to the solid phase magnetic particles. Unbound material is removed by a wash cycle and isoluminol-antibody conjugates are added. During the second incubation, the antibody conjugates react with anti-*Borrelia burgdorferi* IgG and IgM antibodies that are already bound to the solid phase. The second incubation is followed by a wash cycle to remove unbound conjugate. Subsequently, the start reagents are added and a flash chemiluminescence reaction is thus induced. The light signal and hence the amount of isoluminol–antibody conjugate is measured by a photomultiplier as relative light units (RLU) and is indicative of the presence of *Borrelia burgdorferi* antibodies present in calibrators, controls or samples.

PERFORMANCE DATA:

Performance testing of the LIAISON® *Borrelia burgdorferi* Assay for comparative clinical trials consisted of running selected samples to support the intended use.

COMPARATIVE CLINICAL TRIALS: The clinical trials were conducted at two external US laboratories and at DiaSorin, Inc. Testing was performed on prospective and retrospective samples. The samples were tested by LIAISON® *Borrelia burgdorferi* and the comparator assay Immunetics® C6 *B. burgdorferi* (Lyme) ELISA™ kit at the trial sites per the manufacturer's instructions for use.
The study consisted of the following samples types and results.

- Lyme Disease Testing Patients: Prospective samples (n=1038).

	Percent Agreement		95% Confidence Interval
Positive	70.0%	(35/50)	57.6 – 80.5%
Negative	99.1%	(973/982)	98.4 – 99.5%
Overall	97.1%	(1008/1038)	96.1 – 97.9%

Forty-five samples were positive or equivocal by LIAISON® *Borrelia burgdorferi* in the 1038 prospective sample study. These 45 samples were then tested following the two step method with a standardized Western Blot assay (MarDx Marblot Western Blot IgG and IgM assay). Twenty-two of the 45 total samples were W. Blot positive. Of the 22 samples that were Western Blot positive, 6 were IgM +, 12 were IgG +, and 4 were both IgM and IgG +.
Fifty-six samples were positive or equivocal by the Immunetics® C6 *B. burgdorferi* (Lyme) ELISA™. These 56 samples were also tested following the two step method. Twenty-three of the 56 total samples were W. Blot positive. Of the 23

samples that were Western Blot positive 6 were IgM +, 13 were IgG +, and 4 were both IgM and IgG +. A summary of the results are in the following table.

Assay	Result	n	Combined IgG and IgM W. Blot results	
			+	-
LIAISON	+	41	22	19
	±	4	0	4
C6 ELISA	+	50	23	27
	±	6	0	6

- Apparently Healthy Adult Blood Donors: Prospective samples from areas where Lyme disease is Endemic (n= 300) and Non-Endemic (n = 300). Reactivity/Prevalence in the Normal population was determined from these samples types.

Population	N	Negative	Equivocal	Positive	% Positive Prevalence
Endemic	300	297	1	2	0.7%
Non-Endemic	300	299	0	1	0.3%

- Characterized Lyme Disease Samples. Retrospective samples provided by the Centers for Disease Control and Prevention (n=60).

	Percent Agreement		95% Confidence Intervals
Positive	93.2%	(41/44)	83.3 – 98.1%
Negative	81.3%	(13/16)	58.3 – 94.5%
Overall	90.0%	(54/60)	83.3 – 95.5%

- LYMErix™ Vaccine Recipients: Retrospective samples (n=11). (LYMErix® manufactured by GlaxoSmithKline Biologicals)

	Immunetics® C6 Lyme ELISA	
	Pre vaccine Negative	Post vaccine Negative
LIAISON® *Borrelia burgdorferi* Assay	3 /3 (100%) 95% CI = 36.9 - 100%	11/ 11 (100%) 95% CI = 76.1 - 100%

- CDC Lyme serum panel: (n = 42)
  The samples are categorized as Normals (no Lyme Disease n=5). The remaining 37 samples have a clinical diagnosis of Lyme Disease and are presented as Time from Onset of disease.

		LIAISON® *Borrelia burgdorferi*			
Time after Onset	Total	Pos	Eqv	Neg	% Agreement
Normals	5	0	0	5	100%
0-1 Month	6	5	0	1	83.3%
1-2 Months	8	6	0	2	75.0%
3-12 Months	15	8	0	7	53.3%
> 1 year	8	8	0	0	100%
Total	42	27	0	15	73.0%

Conclusion:
The results demonstrate that the LIAISON® *Borrelia burgdorferi* assay can be used with the LIAISON® Analyzer for the qualitative presumptive detection of IgG and IgM antibodies to *Borrelia burgdorferi* in human serum.

REPRODUCIBILITY: Reproducibility studies were performed at 3 sites using a coded panel comprised of 6 prepared serum samples. The same coded panel was tested at all 3 sites following CLSI EP15-A2. Panel samples were tested in four replicates per run, in one run per day, during five operating days.
The results expressed for Index and RLU's are summarized in the tables below.

Index Reproducibility

sample ID#	sample matrix	N	mean Index	Within run %CV	between run %CV	total (by site) %CV	between site %CV	overall %CV
NC	Serum	60	0.06	6.77	8.26	10.93	15.64	17.28
PC	Serum	60	1.95	5.07	5.92	7.37	5.14	8.68
BPP1	Serum	60	0.90	5.38	9.49	10.68	11.70	14.42
BPP2	Serum	60	1.01	3.94	9.07	9.24	6.19	11.31
BPP3	Serum	60	6.8	3.96	6.34	7.68	2.01	8.66
BPP4	Serum	60	1.84	3.45	7.85	8.06	4.21	10.19
BPP5	Serum	60	0.44	6.10	12.19	12.66	13.76	17.57
BPP6	Serum	60	0.13	5.88	10.66	11.67	8.04	13.81

RLU Reproducibility

sample ID#	matrix	N	mean RLU	within run %CV	between run %CV	total (by site) %CV	between site %CV	overall %CV
NC	Serum	60	1516	5.76	6.10	8.17	5.78	9.74
PC	Serum	60	44293	3.96	4.58	5.80	8.85	9.58
BPP1	Serum	60	21243	4.90	7.37	8.85	8.12	11.79
BPP2	Serum	60	23720	3.52	7.78	8.03	4.63	10.24
BPP3	Serum	60	143757	3.88	6.06	7.41	5.63	9.77
BPP4	Serum	60	42016	3.27	6.79	7.21	6.34	10.73
BPP5	Serum	60	10769	5.73	10.23	11.01	7.61	14.31
BPP6	Serum	60	3320	5.82	8.08	9.64	6.57	12.58

Studies were tested internally at DiaSorin Inc. using the same coded panel following CLSI EP5-A2. Samples were tested in 2 replicates per run, on 2 different instruments 2 times per day for 20 days. The results are in the following table.

ID	N	Mean Index	within run SD	within run %CV	between run SD	between run %CV	between instrument SD	between instrument %CV	overall SD	overall %CV
Neg QC-A	160	0.07	0.00	4.12	0.01	8.02	0.00	1.91	0.01	9.24
Pos QC-A	160	2.11	0.07	3.42	0.17	8.08	0.05	2.42	0.19	8.85
BPP1	160	1.11	0.03	3.12	0.08	7.64	0.02	1.63	0.09	8.22
BPP2	160	1.36	0.08	6.10	0.12	9.18	0.01	0.71	0.19	14.03
BPP3	160	7.6	0.36	4.65	0.50	6.59	0.16	2.14	0.70	9.12
BPP4	160	2.22	0.07	3.18	0.17	7.48	0.05	2.11	0.18	8.06
BPP5	160	0.62	0.02	3.67	0.05	8.81	0.02	3.16	0.06	9.49
BPP6	160	0.18	0.01	5.59	0.01	8.24	0.00	0.35	0.03	14.20

Conclusion:
The material submitted in this premarket notification supports a substantial equivalence claim. The labelling is sufficient and satisfies the requirements of 21CFR 809.10.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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APR 12 2007

Re: k062473
Trade/Device Name: LIAISON® *Borrelia burgdorferi*
LIAISON® *Borrelia burgdorferi* Serum Controls
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema pallidum treponemal test reagents
Regulatory Class: Class II
Product Code: LSR
Dated: February 2, 2007
Received: February 5, 2007

Dear Ms. DePouw:

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.

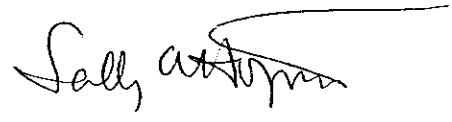
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
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Office of *In Vitro* Diagnostic Device
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Enclosure

Indications for Use

510(k) Number (if known): K062473

Device Name: LIAISON® *Borrelia burgdorferi*

Indications For Use: The LIAISON® *Borrelia burgdorferi* assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® Analyzer for the qualitative presumptive detection of IgG and IgM antibodies to VlsE (variable major protein-like sequence, expressed) protein antigen of *Borrelia burgdorferi* in human serum. This assay should be used only on samples from patients with signs and symptoms that are consistent with Lyme disease. Positive or equivocal results should be supplemented by testing with a standardized Western blot procedure. Positive supplemental results provide evidence of exposure to *Borrelia burgdorferi* and can be used to support a clinical diagnosis of Lyme disease. Negative results by LIAISON® *Borrelia burgdorferi* should not be used to exclude Lyme disease.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

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Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062473

Indications for Use

510(k) Number (if known): K062473

Device Name: LIAISON® *Borrelia burgdorferi* Serum Controls

Indications For Use: The LIAISON® *Borrelia burgdorferi* Serum Controls contains two assayed quality control sera (negative and positive) that are used to monitor the performance of the LIAISON® *Borrelia burgdorferi* assay.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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510(k) K062473