February 18, 2021

Carol Depouw
Principal Regulatory Affairs Specialist
1951 Northwestern Avenue
Stillwater, Minnesota 55082

Re: K202573
Trade/Device Name: LIAISON Lyme IgM, LIAISON Lyme IgM Control Set, LIAISON Lyme Total Antibody Plus
Regulation Number: 21 CFR 866.3830
Regulation Name: Treponema Pallidum Treponemal Test Reagents
Regulatory Class: Class II
Product Code: LSR
Dated: September 2, 2020
Received: September 4, 2020

Dear Carol 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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Maria Ines Garcia, Ph.D.
Branch Chief
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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)*

Device Name
LIAISON® Lyme IgM assay:
LIAISON® Lyme IgM Control Set

Indications for Use *(Describe)*

The LIAISON® Lyme IgM assay uses chemiluminescent immunoassay (CLIA) technology for the qualitative detection of IgM antibodies to Borrelia burgdorferi in human serum and plasma samples (K2-EDTA, Li-heparin). This assay is intended for use on samples from patients with signs and symptoms consistent with or patients suspected of having Lyme disease to assess the presence of antibodies and exposure to Borrelia burgdorferi. In addition, the LIAISON® Lyme IgM assay may be used as a confirmatory test in the modified two-tier test (MTTT) in combination with the DiaSorin LIAISON® Lyme Total Antibody Plus assay.

If used as a first stage test, positive or equivocal results with the LIAISON® Lyme IgM assay should be confirmed through additional testing with a Standard two-tier test (STTT) methodology using an IgM Borrelia burgdorferi Western blot test following current guidelines.

Positive supplemental results are supportive evidence of the presence of antibodies and exposure to Borrelia burgdorferi and may be used along with patient history, symptoms and other laboratory data to support a clinical diagnosis of Lyme disease.
Negative results by the LIAISON® Lyme IgM assay should not be used to exclude Lyme disease.

The test must be performed on the LIAISON® XL Analyzer.

The DiaSorin LIAISON® Lyme IgM Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® Lyme IgM assay. The performance characteristics of LIAISON® Lyme IgM controls have not been established for any other assays 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.

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510(k) SUMMARY

SUBMITTED BY:

Carol A. DePouw
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Phone (651) 439-9710
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Email carol.depouw@diasorin.com

DATE PREPARED: May 05, 2020

NAME OF DEVICE:

Trade Name:	LIAISON® Lyme IgM LIAISON® Lyme IgM Control Set
Common Names/Descriptions:	*Borrelia burgdorferi IgM* assay and *Borrelia burgdorferi IgM* controls
Classification Names:	Treponema pallidum; treponemal test reagents Class II, 21 CFR: 866.3830; Microbiology
Product Code:	LSR and QCH
Predicate Device:	ZEUS ELISA Borrelia burgdorferi IgM Test System (K900196)/modified (K191240)

INTENDED USE:

The LIAISON® Lyme IgM assay uses chemiluminescent immunoassay (CLIA) technology for the qualitative detection of IgM antibodies to *Borrelia burgdorferi* in human serum and plasma samples (K2-EDTA, Li-heparin). This assay is intended for use on samples from patients with signs and symptoms consistent with or patients suspected of having Lyme disease to assess the presence of antibodies and exposure to *Borrelia burgdorferi*. In addition, the LIAISON® Lyme IgM assay may be used as a confirmatory test in the modified two-tier test (MTTT) in combination with the DiaSorin LIAISON® Lyme Total Antibody Plus assay.

If used as a first stage test, positive or equivocal results with the LIAISON® Lyme IgM assay should be confirmed through additional testing with a Standard two-tier test (STTT) methodology using an IgM *Borrelia burgdorferi* Western blot test following current guidelines.

Positive supplemental results are supportive evidence of the presence of antibodies and exposure to *Borrelia burgdorferi* and may be used along with patient history, symptoms and other laboratory data to support a clinical diagnosis of Lyme disease.

Negative results by the LIAISON® Lyme IgM assay should not be used to exclude Lyme disease. The test must be performed on the LIAISON® XL Analyzer.

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

KIT DESCRIPTION:

The LIAISON® Lyme IgM assay is an indirect chemiluminescence immunoassay (CLIA) for the qualitative detection of IgM antibodies to *Borrelia burgdorferi* in human serum and plasma samples. All assay steps (with the exception of magnetic particle resuspension) and incubations are performed by the Analyzer. The principal components of the test are magnetic particles (solid phase) coated with recombinant *Borrelia* antigens and a conjugate reagent containing an anti-human IgM mouse monoclonal antibody 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. Unbound material is then removed with a wash cycle. During the second incubation, the antibody conjugate reacts with anti-*Borrelia burgdorferi* IgM antibodies that have bound to the solid phase. Excess antibody conjugate is then removed with a wash cycle. Subsequently, the starter reagents are added and a flash chemiluminescence reaction is 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* IgM antibodies present in calibrators, samples or controls.

COMPARISON TO PREDICATE DEVICE

Table 1: Table of Similarities

Characteristic	Candidate Device LIAISON® Lyme IgM	Predicate Device ZEUS ELISA *Borrelia burgdorferi* IgM Test System – K900196/K191240
Intended Use	Qualitative detection of IgM antibodies to *Borrelia burgdorferi* in human serum and plasma samples. This assay is intended for use on samples from patients with signs and symptoms consistent with or patients suspected of having Lyme disease to assess the presence of antibodies and exposure to *Borrelia burgdorferi.* In addition, the LIAISON® Lyme IgM assay may be used as a confirmatory test in the modified two-tier test (MTTT) in combination with the DiaSorin LIAISON® Lyme Total Antibody Plus assay. If used as a first stage test, positive or equivocal results with the LIAISON® Lyme IgM assay should be confirmed through additional testing with a Standard two-tier test (STTT) methodology using an IgM *Borrelia burgdorferi* Western blot test following current guidelines. Positive supplemental results are supportive evidence of the presence of antibodies and exposure to *Borrelia burgdorferi* and may be used along with patient history, symptoms and other laboratory data to support a clinical diagnosis of Lyme disease. Negative results by the LIAISON® Lyme IgM assay should not be used to exclude Lyme disease.	Qualitative detection of IgM class antibody to *Borrelia burgdorferi* in human serum. The assay is intended for testing serum samples from symptomatic patients or those suspected of Lyme Disease. Positive and equivocal test results with the ZEUS ELISA *Borrelia burgdorferi* IgM Test System for the presence of *Borrelia burgdorferi* antibodies must be confirmed through additional testing by one of the following approaches: (1) Standard two-tier test methodology (STTT) using IgM Western blot testing following current guidelines; or - (2) Modified two-tier test methodology using the ZUES ELISA Borrelia VlsE1/pepC10 IgG/IgM Test System. Positive test results by either the STTT or MTTT methodology are supportive evidence for the presence of antibodies and exposure to *Borrelia burgdorferi*, the cause of Lyme disease. A diagnosis of Lyme disease should be made based on the presence of *Borrelia burgdorferi* antibodies history, symptoms and other laboratory data.
Results	Qualitative	Same

Characteristic	Candidate Device LIAISON® Lyme IgM	Predicate Device ZEUS ELISA *Borrelia burgdorferi* IgM Test System – K900196/K191240
Measurand	IgM antibodies to *Borrelia burgdorferi*	Same
Intended Population	Patients with signs and symptoms consistent with *Borrelia* infection (Lyme disease)	Same
Assay Principle	Uses *Borrelia* antigens coated on a solid phase to capture specific patient IgM antibodies.	Uses *B. burgdorferi* antigen on coated solid phase (wells) to bind with IgM antibodies in patient sample
Conjugate antibody specificities	Anti-human IgM	Anti-human IgM
Assay Output	Index	Same

Table 2: Table of Differences

Feature	Candidate Device LIAISON® Lyme IgM	Predicate Device ZEUS ELISA *Borrelia burgdorferi* IgM Test System – K900196/K191240
Test Format	CLIA (indirect chemiluminescent assay)	ELISA
Sample Type	Human serum, serum separator tubes, K_2-EDTA, lithium heparin plasma	Human serum
Reporter Molecule	Isoluminol derivative conjugated to anti-human IgM	TMB (as a substrate for Horseradish peroxidase conjugated to anti-human IgM).
Antigen	Recombinant antigens: OspC (*B. afzelii strain pKo).*and VlsE (*B. burgdorferi* strain B31)	Whole cell antigen from *B. burgdorferi (B31 strain)*
Assay Procedure	Automated (on the LIAISON® XL Analyzer)	Manual
Calibration	Two-point verification (in triplicate) of stored 10 point master curve	Single Cut-off Calibrator assayed in triplicate
Output Signal	Flash chemiluminescent response is integrated over a 3 second reading period to generate a relative light unit	Microtiter well O.D. (450 nm) is measured after the enzyme reaction is halted by 1M H_2SO_4/0.7M HCl.
Measurement System	Photomultiplier (flash chemiluminescence reader)	Spectrophotometer (EIA Microtiter plate reader)

PERFORMANCE DATA:

METHOD COMPARISON:

Two thousand six hundred twenty one (2621) human serum specimens were collected in 14 states which represented five (5) distinct U.S. geographical regions. Of the 2621 samples: 44.1% were male, 55.7% were female, 0.2% gender unknown, the ages ranged from 2 years to 103 years of age.

Testing with the LIAISON® Lyme IgM assay on the LIAISON® XL was performed in three (3) laboratories (2 external and internally at DiaSorin).

Table 3: First Tier Percent Agreement with Predicate Device

	Predicate Assay (ELISA IgM)			
LIAISON Lyme IgM	Positive	Equivocal	Negative	Total
Positive	164	8	51	223
Equivocal	13	5	28	46
Negative	87	59	2206	2352
Total	264	72	2285	2621

Agreement Results

Positive % Agreement*	56.5% (190/336)	95% CI: 51.2% - 61.7%
Negative % Agreement	96.5% (2206/2285)	95% CI: 95.7% - 97.2%

*****Includes Positive and Equivocal combined

Standard Two-Tier Testing Methodology:
Western blot testing was performed on the samples that were positive or equivocal by the test device and the predicate following the current guidelines for Standard Two-Tier testing methodology. The following results were obtained:

Table 4: Standard Two-Tier Western Blot

Test System	**Tier 1 + or Eqv**	**WB IgM +**	**WB IgM -**
Predicate assay	336	119	217
LIAISON® Lyme IgM	269	125	144
Predicate assay + LIAISON® Lyme IgM	190	109	81

Agreement Results:

2nd Tier PPA	91.6% (109/119)	95%CI: 85.2% - 95.4%
2nd Tier NPA	99.4% (2486/2502)	95%CI: 99.0% - 99.6%

Modified Two Tier Testing Methodology – Prospective Population
All 2621 prospective (all comer) specimens were tested with the first-tier assay, LIAISON® Lyme Total Antibody Plus. There were 202 positive and 23 equivocal results. In the STTT protocol, the specimens that are positive or equivocal (n=225) are then tested with a *B. burgdorferi* (IgM) Western Blot.
Using the MTTT algorithm, the positive/equivocal specimens (n=225) were tested on the LIAISON® Lyme IgM assay. The second-tier LIAISON® Lyme IgM equivocal and positive results were considered positive. The equivocal and positive results were added together, and the results compared with the STTT positive results. The results obtained are shown in Table 5.

Table 5: MTTT LIAISON Lyme IgM compared to STTT WB IgM

		WB-STTT (IgM)		
		+	-	Total
XL -MTTT (IgM)	+	93	53	146
	-	7	72	79
	Total	100	125	225

Agreement Results

PPA:	93.0% (93/100)	95% CI: 86.3% - 96.6%
NPA:	57.6% (72/225)	95% CI: 48.8% - 65.9%

Characterized Lyme Panel:

Two hundred eighty samples of various reactivity were acquired from the CDC and evaluated internally at the manufacture's site. The results of the testing are presented here as a means of conveying further information on the performance of the LIAISON® Lyme IgM assay with a characterized serum panel. This does not imply an endorsement of the assay by the CDC.

Table 6: Testing of CDC Lyme Reference Sera

CDC Reference Classification									
Sample Category	N	**LIAISON Lyme IgM**				**Predicate IgM**			
		Pos	Neg	Eqv	PPA 95% Wilson CI	Pos	Neg	Eqv	PPA 95% Wilson CI
Acute	39	27	11	1	71.8% (28/39) 56.2% - 83.5%	28	10	1	74.4% (29/39) (58.9% - 85.4%)
Convalescent	31	26	4	1	87.1% (27/31) 71.1% - 94.9%	25	6	0	80.6% (25/31) (63.7% - 90.8%)
Late	20	9	11	0	45.0% (9/20) 25.8% - 65.8%	17	2	1	90.0% (18/20) (69.9% - 97.2%)
Look-alike Diseases	90	6	80	4	88.9% (80/90) 80.7% - 93.9%	8	79	3	87.8% (79/90) (79.4% - 93.0%)
Healthy controls	100	2	97	1	97.0% (97/100) 91.5% - 99.0%	2	97	1	97.0% (97/100) (91.5% - 99.0%)

Modified Two Tier Testing Methodology-Retrospective population

The 280 retrospective samples from the CDC were first tested with the LIAISON® Lyme Total Antibody Plus. One (1) sample, belonging to endemic negative control group, did not have sufficient volume for testing; therefore 279 retrospective samples were evaluated. The LIAISON® Lyme Total Antibody Plus assay yielded 82 positive and equivocal samples. The 82 positive and equivocal samples were then tested by the IgM Western Blot (STTT) or the LIAISON® Lyme IgM assay (MTTT). The results of MTTT-IgM compared to WB-STTT (IgM).

	Stage I (n=60)		Stage II (n=10)		Stage III (n=20)		Healthy Controls (n=99)		Disease Controls (n=90)	
	STTT WB IgM	MTTT XL IgM	STTT WB IgM	MTTT XL IgM	STTT WB IgM	MTTT XL IgM	STTT WB IgM	MTTT XL IgM	STTT WB IgM	MTTT XL IgM
Positive	30	44	9	9	7	9	0	0	0	0
Negative	30	16	1	1	13	11	99	99	90	90
Sensitivity or PPA	50.0 %	73.3 %	90.0 %	90.0 %	35.0 %	45.0 %	N/A	N/A	N/A	N/A
Specificity or NPA	N/A	N/A	N/A	N/A	N/A	N/A	100%	100%	100%	100%

PRECISION STUDY

A 12 day precision/repeatability was conducted at DiaSorin Inc. on 2 lots of the LIAISON® Lyme IgM assay. Six (6) serum samples and two (2) lots of LIAISON® Lyme IgM Controls were tested for 12 days, 2 runs/day, and 2 reps per run by multiple technicians for a total of 48 replicates per lot spanning 2 calibration cycles. One (1) lot is presented below.

The CLSI Document EP5-A3 was consulted in the preparation of the testing protocol.

Sample ID	N	Mean	Within Run		Between Run		Between Day		TOTAL (Within-lot)	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative Control Lot 1	48	2550*	84.7	3.3%	95.6	3.8%	53.1	2.1%	138.4	5.4%
Positive Control Lot 1	48	2.39	0.06	2.3%	0.07	2.8%	0.14	6.0%	0.17	7.0%
Negative Control Lot 2	48	1500*	50.9	3.4%	50.7	3.4%	39.4	2.6%	81.9	5.5%
Positive Control Lot 2	48	2.33	0.08	3.5%	0.00	0.0%	0.13	5.5%	0.15	6.3%
LM-QC3	48	1.54	0.06	3.8%	0.00	0.0%	0.1	6.8%	0.12	7.8%
LM-QC11	48	1.51	0.03	2.3%	0.06	3.7%	0.07	4.9%	0.1	6.5%
LM-QC12	48	4.65	0.12	2.7%	0.08	1.8%	0.31	6.6%	0.34	7.3%
LM-QC13	48	0.29	0.01	2.9%	0.01	4.5%	0.02	7.1%	0.03	8.9%
LM-QC16	48	0.8	0.04	4.5%	0.01	1.8%	0.06	7.4%	0.07	8.8%
LM-QC17	48	0.78	0.02	3.0%	0.01	1.3%	0.05	6.9%	0.06	7.6%

*RLU - Index was below measuring range of assay

REPRODUCIBILITY STUDY

A five (5) day precision/reproducibility study was performed internally at DiaSorin Inc. and at two (2) external U.S. laboratories with one (1) lot of the LIAISON® Lyme IgM assay.

The study was performed for 5 days, 2 runs/day, and 3 replicates/run. Each day, two operators, at each testing site performed the testing for a total of 30 replicates at each site. CLSI document EP15-A3 was consulted in the preparation of the testing protocol.

Sample ID	n	mean	Within Run		Between Day		Between Run		Between Site		TOTAL	
			SD	%CV	SD	%CV	SD	%CV	SD	%CV	SD	%CV
Negative Control	90	1277*	56.99	4.5%	29.39	2.3%	0.000	0.0%	331.56	26.0%	337.7	26.4%
Positive Control	90	2.74	0.104	3.8%	0.082	3.0%	0.077	2.8%	0.104	3.8%	0.185	6.8%
LM-QC3	90	1.62	0.050	3.1%	0.047	2.9%	0.036	2.2%	0.103	6.4%	0.129	8.0%
LM-QC11	90	1.50	0.048	3.2%	0.056	3.8%	0.020	1.4%	0.061	4.1%	0.098	6.5%
LM-QC12	90	4.40	0.105	2.4%	0.047	1.1%	0.078	1.8%	0.139	3.2%	0.197	4.5%
LM-QC13	90	0.312	0.012	3.8%	0.015	4.8%	0.000	0.0%	0.043	13.9%	0.047	15.2%
LM-QC16	90	0.791	0.028	3.6%	0.029	3.7%	0.011	1.4%	0.045	5.6%	0.061	7.7%
LM-QC17	90	0.774	0.024	3.1%	0.03	3.9%	0.013	1.7%	0.056	7.2%	0.069	9.0%

*RLU - Index was below measuring range of assay

CROSS-REACTIVITY STUDY

The cross-reactivity study was designed to evaluate 191 specimens from nineteen (19) disease states either known to contain potentially cross reactive antibodies to *B. burgdorferi* or from patients with diagnoses that can exhibit signs and symptoms similar to Lyme disease and cause false positive results.

Organism Infected or Disease State	Samples Tested (n)	Pos or Eqv
Tick Borne Diseases		
Anaplasmosis IgM	1	1
Babesiosis IgM	10	4^
Autoimmune Disorders		
Anti-Nuclear Antibodies (ANA)	10	0
Multiple Sclerosis	10	0
Viral Diseases		
Cytomegalovirus (CMV) IgM	10	1^
Epstein-Barr Virus (EBV) VCA and/or heterophile Ab IgM	10	0
Epstein-Barr Virus (EBV) VCA IgM	10	2$
Herpes Simplex Virus (HSV) IgM	10	1^
Human Immunodeficiency Virus (HIV)	10	0
Influenza Virus	10	0
Parvovirus IgM	10	1
Varicella Zoster Virus (VZV) IgM	10	1^
Bacterial Diseases		
H. pylori	10	0
Syphilis	10	2
Rheumatic Diseases		
Fibromyalgia	10	0
Rheumatoid Arthritis	10	0
Rheumatoid Factor	10	1^
Systemic Lupus Erythematosus (SLE)	10	1
Additional Markers		
Chronic Fatigue Syndrome	10	0
Human Anti-mouse Antibodies (HAMA)	10	1
Total	**191**	**16**

INTERFERING SUBSTANCES

"Controlled studies of potentially interfering substances from endogenous interferents spiked into serum specimens containing *B. burgdorferi* IgM antibodies at levels near the cut-off showed that assay performance was not affected at the concentration for each substance listed below. The testing was based on CLSI-EP7-A3.

Substances	Tested Concentrations
Hemoglobin	1000 mg/dL
Triglycerides	1500 mg/dL
Bilirubin	40 mg/dL
Total protein	12 g/dL
Cholesterol	400 mg/dL
Biotin	3600 ng/mL

MATRIX EQUIVALENCE STUDY:

Thirty-two (32) matched patient sets of serum, SST serum, K_2-EDTA plasma and lithium heparin plasma samples were tested to determine if these sample types provide equivalent results. Sample regression analysis was done by Passing & Bablok regression. All sample types met acceptance criteria for use in the LIAISON® Lyme IgM assay. A summary of the results are shown in the following table.

Comparison to Serum		Bias	95% CI
Serum SST	Constant	-0.01	-0.03 to 0.00
	Proportional	1.03	1.00 to 1.06
EDTA Plasma	Constant	-0.02	-0.05 to 0.03
	Proportional	1.03	0.97 to 1.08
Lithium Heparin Plasma	Constant	-0.02	-0.05 to -0.00
	Proportional	1.03	1.00 to 1.07

CONCLUSION:

The material submitted in this premarket notification supports a substantial equivalence decision. The labelling satisfies the requirements of 21CFR 809.10.