DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 27, 2018

DiaSorin Inc.
Carol A DePouw
Regulatory Affairs Specialist
1951 Northwestern Ave.
Stillwater, MN 55082-0285 US

Re: K173683
Trade/Device Name: LIAISON BRAHMS PCT II GEN assay, LIAISON Control BRAHMS PCT II GEN and LIAISON BRAHMS PCT II GEN Verifiers
Regulation Number: 21 CFR 866.3215
Regulation Name: Device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis
Regulatory Class: II
Product Code: PMT, NTM, JJX
Dated: November 30, 2017
Received: December 1, 2017

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. 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

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® B.R.A.H.M.S PCT® II Gen
LIAISON® Control B.R.A.H.M.S PCT® II Gen
LIAISON® B.R.A.H.M.S PCT® II Gen Verifiers

Indications for Use *(Describe)*

The LIAISON® B.R.A.H.M.S PCT® II GEN assay uses chemiluminescence immunoassay (CLIA) technology for the in vitro quantitative determination of Procalcitonin in human serum and lithium heparin plasma specimens. Used in conjunction with other laboratory findings and clinical assessments, LIAISON® B.R.A.H.M.S PCT® II GEN is intended for use as follows:

- to aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock,

- to aid in assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with severe sepsis or septic shock in the ICU or when obtained in the emergency department or other medical wards prior to ICU admission, using a change in PCT level over time,

- to aid in decision making on antibiotic therapy for patients with suspected or confirmed lower respiratory tract infections (LRTI) defined as community-acquired pneumonia (CAP), acute bronchitis, and acute exacerbation of chronic obstructive pulmonary disease (AECOPD) – in an inpatient setting or an emergency department,

- to aid in decision making on antibiotic discontinuation for patients with suspected or confirmed sepsis.

The LIAISON® Control B.R.A.H.M.S PCT® II GEN (level 1 and level 2) are intended for use as assayed quality control samples to monitor the performance and reliability of the LIAISON® BRAHMS PCT® II GEN assay. The performance characteristics of LIAISON® BRAHMS PCT® II GEN controls have not been established with any other assay or instrument platform different from the LIAISON® Analyzer.

The LIAISON® B.R.A.H.M.S PCT® II GEN Verifiers (four levels) are assayed quality control materials intended in the quantitative verification of calibration and reportable range of the LIAISON® BRAHMS PCT® II GEN assay. The performance characteristics of LIAISON® BRAHMS PCT® II GEN calibration verifiers have not been established in connection with any other assay or instrument platforms different from the LIAISON® Analyzer.

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

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NAME OF DEVICE:

Trade Name:	LIAISON® BRAHMS PCT® II GEN, LIAISON® Control BRAHMS PCT® II GEN LIAISON® BRAHMS PCT® II GEN Verifiers
Common Names/Descriptions:	Procalcitonin Assay
Classification Names:	Device to detect and measure non microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis 21 CFR 866.3215 (PMT) Procalcitonin Assay 21 CFR 866.3215(PRI)
Product Code:	PRI, PMT, NTM, JJX

PREDICATE DEVICES: VIDAS® B·R·A·H·M·S PCT™ (K162827)

DEVICE DESCRIPTION:

INTENDED USE:

LIAISON® BRAHMS PCT® II GEN assay uses chemiluminescence immunoassay (CLIA) technology for the in vitro quantitative determination of Procalcitonin in human serum and lithium heparin plasma specimens. Used in conjunction with other laboratory findings and clinical assessments, LIAISON® BRAHMS PCT® II GEN is intended for use as follows:

- to aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock,
- to aid in assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with severe sepsis or septic shock in the ICU or when obtained in the emergency department or other medical wards prior to ICU admission, using a change in PCT level over time.
- to aid in decision making on antibiotic therapy for patients with suspected or confirmed lower respiratory tract infections (LRTI) defined as community-acquired pneumonia (CAP), acute bronchitis, and acute exacerbation of chronic obstructive pulmonary disease (AECOPD) – in an inpatient setting or an emergency department,

- to aid in decision making on antibiotic discontinuation for patients with suspected or confirmed sepsis.

The LIAISON® Control BRAHMS PCT® (level 1 and level 2) are intended for use as assayed quality control samples to monitor the performance and reliability of the LIAISON® BRAHMS PCT® II GEN assay. The performance characteristics of LIAISON® BRAHMS PCT® II GEN controls have not been established with any other assay or instrument platform different from the LIAISON® Analyzer.

The LIAISON® BRAHMS PCT® II GEN calibration verifiers (four levels) are assayed quality control materials intended in the quantitative verification of calibration and reportable range of the LIAISON® BRAHMS PCT® II GEN assay. The performance characteristics of LIAISON® BRAHMS PCT® II GEN calibration verifiers have not been established in connection with any other assay or instrument platforms different from the LIAISON® Analyzer.

KIT DESCRIPTION:

The method for the quantitative determination of PCT is a sandwich chemiluminescence immunoassay. A specific monoclonal antibody is coated on the magnetic particles (solid phase); another monoclonal antibody (specific for a different epitope of the procalcitonin molecule) is linked to an isoluminol derivative (isoluminol-antibody conjugate).

During the first incubation, PCT present in calibrators, samples or controls binds to the antibody conjugate. Then the solid phase is added to the reaction. A sandwich is formed only in the presence of PCT molecules that bridge both antibodies. After the second incubation, the 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 hence the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) and is indicative of PCT concentration present in calibrators, samples or controls.

COMPARISON TO PREDICATE:

Table 1:	**Table of Similarities**	
Characteristic	**Predicate Device: VIDAS® BRAHMS PCT™ (k162827)**	**Candidate Device: LIAISON® BRAHMS PCT® II GEN (k173683)**
Intended Use/ Indications for use	VIDAS® B·R·A·H·M·S PCT™ (PCT) is an automated test for use on the instruments of the VIDAS® family for the determination of human procalcitonin in human serum or plasma (lithium heparin) using the ELFA (Enzyme-Linked Fluorescent Assay) technique. Used in conjunction with other laboratory findings and clinical assessments, VIDAS® B•R•A•H•M•S PCT™ is intended for use as follows: • to aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock, • to aid in assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with severe sepsis or septic shock in the ICU or when obtained in the emergency department or other medical wards prior to ICU admission, using a change in PCT level over time, • to aid in decision making on antibiotic therapy for patients with suspected or confirmed lower respiratory tract infections (LRTI) – defined as community-acquired pneumonia (CAP), acute bronchitis, and acute exacerbation of chronic obstructive pulmonary disease (AECOPD) – in an inpatient setting or an emergency department, • to aid in decision making on antibiotic discontinuation for patients with suspected or confirmed sepsis.	The LIAISON® B·R·A·H·M·S PCT® II GEN assay uses chemiluminescence immunoassay (CLIA) technology for the *in vitro* quantitative determination of Procalcitonin in human serum and lithium heparin plasma specimens. Used in conjunction with other laboratory findings and clinical assessments, LIAISON® B.R.A.H.M.S PCT® II GEN intended for use as follows: · to aid in the risk assessment of critically ill patients on their first day of ICU admission for progression to severe sepsis and septic shock, · to aid in assessing the cumulative 28-day risk of all-cause mortality for patients diagnosed with severe sepsis or septic shock in the ICU or when obtained in the emergency department or other medical wards prior to ICU admission, using a change in PCT level over time, · to aid in decision making on antibiotic therapy for patients with suspected or confirmed lower respiratory tract infections (LRTI) defined as community-acquired pneumonia (CAP), acute bronchitis, and acute exacerbation of chronic obstructive pulmonary disease (AECOPD) – in an inpatient setting or an emergency department, to aid in decision making on antibiotic discontinuation for patients with suspected or confirmed sepsis.

Sample Matrix	Serum and Lithium Heparin plasma	Serum and Lithium Heparin plasma
Calibrators	Two	Two
Controls	Two (Low and High)	Two (Low and High)
Reagent Storage	2-8°C, Refrigerator	2-8°C onboard or in Refrigerator

Table 2: Table of Differences

Characteristic	**Predicate Device: VIDAS® BRAHMS PCT™ (k162827)**	**Candidate Device: LIAISON® BRAHMS PCT® II GEN (k173683)**
Type of Assay	Enzyme Immunoassay	Chemiluminescent Immunoassay
Detection	ELFA - Enzyme-Linked Fluorescent Assay	CLIA - Chemiluminescence Immunoassay
Sample Handling/processing	Manual	Automated
Detector	Alkaline phosphatase-labeled mouse monoclonal anti-human procalcitonin immunoglobulins	Anti-calcitonin antibody, labelled with isoluminol, monoclonal (mouse)
Capture Reagent	Microwells coated with mouse monoclonal anti-human procalcitonin immunoglobulins	Magnetic particles coated with anti-katacalcin antibody, monoclonal (mouse)
Sample Volume	200 µL	225 µL specimen (75 µL specimen + 150 µL dead volume)
Measurement System	Spectrophotometer (EIA Microtiter plate reader)	Photomultiplier (flash chemiluminescence reader)
Total incubation	20 minutes	40 minutes

Table 3: Control Similarities and Differences

Characteristics	**Predicate Device: VIDAS® BRAHMS PCT™ (k162827)**	**Candidate Device: LIAISON® Controls BRAHMS PCT® II GEN (k173683)**
Intended Use	Intended for use as assayed quality control samples to monitor the performance of the LIAISON® BRAHMS PCT II GEN assay	Same
Matrix	Recombinant human PCT	Recombinant Procalcitonin Antigen
Storage	2-8°C	Same
Quantity and Volume	2 x 2 mL (lyophilized)	2 x 1.1 mL (lyophilized)

Table 4: Calibration Verifiers Similarities and Differences		
Characteristic	**Predicate Device (K141463) - LIAISON® XL 1,25 Dihydroxyvitamin D Calibration Verifiers**	**Candidate Device LIAISON® BRAHMS PCT® II GEN Verifiers (k173683)**
Intended Use	Assayed quality control materials intended for the quantitative verification of calibration and reportable range of the LIAISON XL 1,25 Dihydroxyvitamin D	Assayed quality control materials intended in the quantitative verification of calibration and reportable range of the LIAISON® BRAHMS PCT® II GEN assay.
Product Storage	2 to 8°C until ready to use	Same
Levels	4 levels; lyophilized	Same
Volume	2.0 mLs	1.1 mLs

PERFORMANCE DATA:

Limit of Blank (LoB)*

Following the method from CLSI EP17-A2, the limit of blank for the LIAISON® BRAHMS PCT® II GEN assay is 0.01 ng/mL.

*Limit of Blank, or the highest value likely to be observed with a sample containing no analyte, replaces the term “analytical sensitivity”.

Limit of Detection (LoD)

Following the method from CLSI EP17-A2, the limit of detection for the LIAISON® BRAHMS PCT® II GEN assay is 0.02 ng/mL.

Limit of Quantification (LoQ)

Following the method from CLSI EP17-A2, the limit of quantitation for the LIAISON® BRAHMS PCT® II GEN assay is 0.05 ng/mL (%Bias < 5%, %CV < 15% and %Total error <30%).

A modeling analysis was conducted to evaluate the LOQ and each medical decision point. The Total Error (TE) % was calculated as 1.65*(CV%) + (Bias%). The results from each of three regression (Bias, CV and TE%) are summarized in the table below and were based on fitting the Bias, CV and TE% from 320 data points for each medical decision point (0.10, 0.25, 0.50 and 2 ng/mL) generated from Precision studies and from 60 data points around 0.05 ng/mL (ranging from 0.036 to 0.069 ng/mL) generated from LOQ study.

LOQ and Medical Decision Point

PCT level (ng/mL)	CV%	Bias%	Total Error%
0.05	14.0%	2.7%	25.8%
0.10	15.0%	0.3%	25.1%
0.25	13.0%	1.4%	22.9%
0.50	10.3%	3.0%	19.9%
2.0	6.8%	4.0%	15.3%

COMPARATIVE STUDIES/METHOD COMPARISON:

Quantitative Analysis Study Design

A quantitative method comparison study was performed on 349 serum samples and 20 lithium heparin plasma samples for a total of 369 samples following CLSI EP09-A2.
Of the 369 samples, one hundred four (104) samples were not included in the analysis because they read <0.05 ng/mL which is below the reading range of either or both assays and one (1) sample read > 100 ng/mL on the LIAISON® BRAHMS PCT® II GEN assay and therefore was also removed from the analysis.

The PCT sample results ranged from 0.05 ng/mL to 131 ng/mL.

Weighted Deming analysis was applied to the results across the range of the LIAISON® BRAHMS PCT® II GEN assay yielding agreement of y = 1.07x + 0.03. The 95% confidence intervals for the slope were 1.03 to 1.11 and the 95% confidence intervals for the intercept 0.02 to 0.05 ng/mL.

Table 5: Bias calculated at two medical decision points 0.50 and 2.0 ng mL with 95% CI

Decision level	Bias	95% CI		**Bias Calculation**
0.5	0.06481	0.05021	to 0.07941	**13%**
2	0.16588	0.09894	to 0.23283	**8%**

Qualitative Analysis Study Design - Agreement at Clinical Decision Points

A qualitative method comparison study was also performed on the 369 samples. Results for the LIAISON® BRAHMS PCT® II GEN assay are provided in an agreement table and confidence intervals for each level within a comparison table for the following cut-offs:

a.) ≤ 0.10;	b.) > 0.10 and ≤ 0.25;	c.) > 0.25 and < 0.5;	d.) ≥ 0.5 and < 2.0;	e.) ≥ 2.0;

Table 6: Qualitative Agreement at Clinical Decision points

	Reference Method					
LIAISON® BRAHMS PCT® II GEN	≤0.10 ng/mL	>0.10 and ≤ 0.25 ng/mL	>0.25 and < 0.50 ng/mL	≥0.50 and < 2.0 ng/mL	≥2.0 ng/mL	TOTAL
≤0.10 ng/mL	108	2	0	0	0	110
>0.10 and ≤ 0.25 ng/mL	17	31	3	0	0	51
>0.25 and < 0.50 ng/mL	0	15	27	1	0	43
≥0.50 and < 2.0 ng/mL	0	2	10	50	0	62
≥2.0 ng/mL	0	0	0	3	100	103
TOTAL	125	50	40	54	100	369

REPRODUCIBILITY/PRECISION:

Internal 20-day Precision

A twenty day reproducibility/precision study was performed internally at DiaSorin Inc.
A coded panel comprised of 10 frozen serum samples spanning the assay range was prepared by DiaSorin S.p.A. One lot of LIAISON® Control BRAHMS PCT® II GEN (2 levels) and one lot of LIAISON® BRAHMS PCT® II GEN verifiers (4 levels) were also tested in the study. The CLSI document EP05-A3 was consulted in the preparation of the testing protocol.

The precision panel samples, kit controls and verifiers were tested on two lots of LIAISON® BRAHMS PCT® II GEN in two replicates per run, 2 runs per day for 20 operating days on 1 LIAISON® Analyzer with multiple operators performing the testing The testing spanned at least two calibration cycles.

The 20 day results are summarized in Table 7 for the combined reagent lot numbers as sample mean PCT concentration in ng/mL, computed SDs and %CVs for between lot and Total across lots for each of the tested specimens, kit controls and verifiers.

Table 7: Combined Lot Precision

Sample ID	n	Mean PCT (ng/mL)	Between-Lot		Total (Across Lots)	
			SD	%CV	SD	%CV
Kit Control 1	160	1.36	0.03	2.0%	0.09	6.5%
Kit Control 2	160	45.8	0.25	0.6%	2.82	6.1%
CV A	160	0.47	0.02	3.7%	0.04	8.7%
CV B	160	1.78	0.04	2.1%	0.13	7.0%
CV C	160	6.33	0.10	1.7%	0.35	5.5%
CV D	160	43.6	0.58	1.3%	2.69	6.2%
P001	158*	0.12	0.00	3.1%	0.02	16.6%
P002	158*	0.11	0.01	6.2%	0.02	17.1%
P003	160	0.29	0.01	3.7%	0.03	11.8%
P004	160	0.28	0.00	0.6%	0.03	12.3%
P005	160	0.59	0.01	2.0%	0.05	8.9%
P006	160	0.59	0.00	0.7%	0.06	10.3%
P007	160	2.21	0.03	1.4%	0.22	10.0%
P008	160	2.24	0.04	1.9%	0.15	6.6%
P009	160	24.4	0.17	0.7%	1.84	7.5%
P010	160	67.8	1.06	1.6%	3.74	5.5%

Multi-Site Precision

A five day precision/reproducibility study was performed at two external laboratories and internally at DiaSorin Inc. to verify the precision of the LIAISON® BRAHMS PCT® II GEN assay.

A coded panel comprised of 10 frozen serum samples spanning the assay range was prepared by DiaSorin S.p.A. Two lots of LIAISON® Control BRAHMS PCT® II GEN (2 levels) and two lots of LIAISON® BRAHMS PCT® II GEN verifiers (4 levels) were also tested in the study. The CLSI document EP15-A3 was consulted in the preparation of the testing protocol.

The precision panel samples, kit controls, and verifiers were tested on one lot of LIAISON® BRAHMS PCT® II GEN in three replicates per run, 2 runs per day for 5 operating days on 3 LIAISON® Analyzers with multiple operators performing the testing

Results

The 5 day study results are summarized in table 8 for the 3 sites combined. The 3 sites combined data includes sample mean, SD and % CV for With-in run, Between day, Site to Site, and Total.

Table 8: 5 day Combined Site Precision

Sample ID	Mean PCT (ng/mL)	Within Run		Between Day		Site to Site		Total	
		SD	%CV	SD	%CV	SD	%CV	SD	%CV
Kit Control 1 Lot 1	1.4	0.05	3.2%	0.05	3.8%	0.07	5.2%	0.10	7.1%
Kit Control 2 Lot 1	42.92	1.08	2.5%	2.15	5.0%	2.34	5.4%	3.32	7.7%
Kit Control 1 Lot 2	1.39	0.04	3.1%	0.05	3.6%	0.08	5.6%	0.10	7.3%
Kit Control 2 Lot 2	46.25	1.77	3.8%	1.82	3.9%	1.27	2.7%	2.75	5.9%
CV A Lot 1	0.48	0.03	5.8%	0.03	5.3%	0.02	4.4%	0.04	8.6%
CV B Lot 1	1.83	0.07	3.6%	0.06	3.4%	0.12	6.6%	0.15	8.1%
CV C Lot 1	6.45	0.19	2.9%	0.21	3.2%	0.36	5.6%	0.45	7.0%
CV D Lot 1	44.31	1.13	2.6%	1.03	2.3%	1.62	3.7%	2.18	4.9%
CV A Lot 2	0.385	0.02	5.8%	0.02	4.6%	0.02	5.8%	0.04	9.1%
CV B Lot 2	1.75	0.05	3.0%	0.05	3.0%	0.07	4.0%	0.10	5.7%
CV C Lot 2	8.48	0.31	3.6%	0.45	5.2%	0.53	6.3%	0.75	8.8%
CV D Lot 2	43.14	0.92	2.1%	1.28	3.0%	1.63	3.8%	2.23	5.2%
P001	0.135	0.01	10.7%	0.01	9.3%	0.01	4.0%	0.02	14.0%
P002	0.129	0.02	12.3%	0.01	6.9%	0.01	10.4%	0.02	16.8%
P003	0.321	0.01	3.6%	0.01	4.0%	0.02	5.5%	0.02	7.6%
P004	0.312	0.03	8.6%	0.02	6.6%	0.02	7.1%	0.04	12.5%
P005	0.651	0.03	3.8%	0.03	4.3%	0.04	5.3%	0.05	7.7%
P006	0.65	0.03	3.9%	0.04	5.4%	0.04	5.9%	0.06	8.8%
P007	2.39	0.06	2.5%	0.08	3.3%	0.14	5.7%	0.17	7.0%
P008	2.43	0.07	2.7%	0.13	5.2%	0.14	5.7%	0.20	8.0%
P009	26.37	0.80	3.0%	1.01	3.8%	0.62	2.3%	1.39	5.3%
P010	70.9	2.76	3.9%	1.90	2.7%	1.28	1.8%	3.40	4.8%

Table 9: STABILITY STUDIES: REAGENTS

LIAISON® BRAHMS PCT® II GEN	
Study	Stability
Calibration Curve	8 weeks
Open Use storage On-board Analyzer	12 weeks
Open Use storage at 2-8°C	12 weeks
Calibrator Freeze/Thaw cycles	3 cycles

LIAISON® Control BRAHMS PCT® II GEN	
Study	Stability
Open Use storage at -20°C	8 weeks
Control Freeze/Thaw cycles	7 cycles
Diluent provided with Controls	
Open Use storage at 2-8°C	3 months

LIAISON® BRAHMS PCT® II GEN Verifiers	
Study	Stability
Open Use storage at -20°C	8 weeks
Cal Verifier Freeze/Thaw cycles	7 cycles

SAMPLE EQUIVALENCY AND STABILITY STUDIES:

Equivalence testing was performed with 40 matched patient samples consisting of serum and lithium heparin collection tubes. Samples spanned the full assay measuring range. Spiked or diluted samples were used in order to span the assay range.

Paired samples were tested in triplicate in the same run using 1 reagent lot and 1 analyzer in order to exclude the effects of other variables on the results.

The (mean) result of each sample type under examination (y) is reported versus the mean result obtained with the reference sample type (x).

Results of the serum and lithium heparin plasma samples were compared by Passing and Bablok and Weighted Deming regression. Human serum and Lithium Heparin Plasma are acceptable sample types for use in the LIAISON® BRAHMS PCT® II GEN assay. A summary of the results are in Table 10 below.

Table 10: Summary of Sample Equivalence Regression analysis

Passing & Bablok			
Slope	1.019	95% CI	1.012 - 1.031
Intercept	0.003	95% CI	-0.003 - 0.006
Weighted Deming			
Slope	0.9998	95% CI	0.9712 - 1.028
Intercept	0.005	95% CI	0.0015 - 0.0079

SAMPLE STABILITY:

Studies were performed to evaluate the stability of samples at different sample storage conditions. The results are provided in the table below.

Table 11: Sample Stability

Specimen	
Study	Stability
Room Temperature (20-25°C)	24 hours
Refrigerated (2-8°C)	24 hours
Frozen (-20°C)	3 months
Freeze/Thaw Cycles	5 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.