DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

January 05, 2017

DIASORIN INCORPORATED
JOHN C. WALTER
PRESIDENT
1951 NORTHWESTERN AVE.
STILLWATER, MN 55082

Re: K162961
Trade/Device Name: LIAISON® VCA IgG and LIAISON® VCA IgG Serum Control Set
LIAISON® EBNA IgG and LIAISON® EBNA IgG Serum Control Set
Regulation Number: 21 CFR 866.3235
Regulation Name: Epstein-Barr virus serological reagents
Regulatory Class: Class I
Product Code: LSE, LLM, JJX
Dated: October 21, 2016
Received: December 6, 2016

Dear Mr. Walter:

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 regulation (21 CFR Part 801), 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" (21CFR 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,

Maria I. Garcia -S
2017.01.05 10:28:34 -05'00'

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162961

Device Name
LIAISON® VCA IgG and LIAISON® VCA IgG Serum Control Set

Indications for Use *(Describe)*
The LIAISON® VCA IgG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® Analyzer family* for the qualitative determination of specific IgG antibodies to Epstein-Barr virus (EBV) viral capsid antigen (VCA) p18 synthetic peptide in human serum. When performed in conjunction with other EBV markers, this assay can be used as an aid in the clinical laboratory diagnosis of Epstein-Barr Viral Syndrome in patients with signs and symptoms of EBV infection such as infectious mononucleosis.

The DiaSorin LIAISON® VCA IgG Serum Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® VCA IgG assay on the LIAISON® Analyzer family*. The performance characteristics of the LIAISON® VCA IgG controls have not been established for any other assay or instrument platforms different from the LIAISON® and LIAISON® XL.

*(LIAISON® and 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162961

Device Name
LIAISON® EBNA IgG and LIAISON® EBNA IgG Serum Control Set

Indications for Use *(Describe)*
The LIAISON® EBNA IgG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® Analyzer family* for the qualitative determination of specific IgG antibodies to Epstein-Barr virus (EBV) nuclear antigen synthetic peptide (EBNA-1) in human serum. When performed in conjunction with other EBV markers, this assay can be used as an aid in the clinical laboratory diagnosis of Epstein-Barr Viral Syndrome in patients with signs and symptoms of EBV infection such as infectious mononucleosis.

The DiaSorin LIAISON® EBNA IgG Serum Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® EBNA IgG assay on the LIAISON® Analyzer family*. The performance characteristics of the LIAISON® EBNA IgG controls have not been established for any other assay or instrument platforms different from the LIAISON® and LIAISON® XL.

*(LIAISON® and 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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Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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510(k) SUMMARY

SUBMITTED BY: DiaSorin Inc.
1951 Northwestern Avenue
P.O. Box 285
Stillwater, MN 55082-0285

CONTACT: Gagan Gill
Regulatory Affairs Associate
Email: gagan.gill@diasorin.com

DATE OF PREPARATION: October 21, 2016

NAME OF DEVICE:

Trade Name: LIAISON® VCA IgG
LIAISON® VCA IgG Serum Control Set

Common Names/Description: Immunoassay for the detection of IgG antibodies to EBV viral capsid antigens (VCA)

Classification: Epstein-Barr Virus, serological reagents; 21 CFR 866.3235; Class I, Microbiology(83)

Product Code: LSE, JJX

PREDICATE DEVICE: DiaSorin LIAISON® VCA IgG (K040120)

DEVICE DESCRIPTION:
The LIAISON® VCA IgG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® Analyzer family for the qualitative determination of specific IgG antibodies to Epstein-Barr virus (EBV) viral capsid antigen (VCA) p18 synthetic peptide in human serum.

The LIAISON® VCA IgG Serum Control Set (negative and positive) consists of liquid ready-to-use controls in human serum/defibrinated plasma. The negative control is intended to provide an assay response characteristic of negative patient specimens and the positive control is intended to provide an assay response characteristic of positive patient specimens.

The controls are designed for use with DiaSorin LIAISON® VCA IgG assay on the LIAISON® Analyzer family.

INTENDED USE:
The LIAISON® VCA IgG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® Analyzer family* for the qualitative determination of specific IgG antibodies to Epstein-Barr virus (EBV) viral capsid antigen (VCA) p18 synthetic peptide in human serum. When performed in conjunction with other EBV markers, this assay can be used as an aid in the clinical laboratory diagnosis of Epstein-Barr Viral Syndrome in patients with signs and symptoms of EBV infection such as infectious mononucleosis.

The DiaSorin LIAISON® VCA IgG Serum Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® VCA IgG assay on the LIAISON® Analyzer family*. The performance characteristics of the LIAISON® VCA IgG controls have not

been established for any other assay or instrument platforms different from the LIAISON® and LIAISON® XL.

*(LIAISON® and LIAISON® XL).

COMPARISON TO THE PREDICATE (Description of the Modifications to the Legally Marketed Device):

The following table provides a summary of the FDA cleared LIAISON® VCA IgG assay.

LIAISON® VCA IgG assay		
Characteristic	**Predicate Device DiaSorin LIAISON® VCA IgG K040120, Cleared 06/01/2005**	**DiaSorin LIAISON® VCA IgG**
Intended Use/Indications for Use	The LIAISON® VCA IgG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® Analyzer family* for the qualitative determination of specific IgG antibodies to Epstein-Barr virus (EBV) viral capsid antigen (VCA) p18 synthetic peptide in human serum. When performed in conjunction with other EBV markers, this assay can be used as an aid in the clinincal laboratory diagnosis of Epstein-Barr Viral Syndrome in patients with signs and symptoms of EBV infection such as infectious mononucleosis. *(LIAISON® and LIAISON® XL).	No Change
Technology/ Assay Principle	Chemiluminescent Immunoassay (CLIA)	No Change
Sample Handling/Assay Processing	Automated	No Change
Storage	Store at 2-8º C until ready to use	No Change
Measured Analyte	IgG antibodies to Epstein-Barr virus (EBV) viral capsid antigen	No Change
Assay Performance Characteristics	No Change	No Change
Labeling (IFU)	References buffer based controls	References serum based controls
Controls	Provided Separately	No Change

Changes to the DiaSorin LIAISON® VCA IgG Serum Control Set include a 100% serum/defibrinated plasma based matrix and the extension of the open use stability claim.

The following tables provide a summary of the similarities and differences between the FDA cleared LIAISON® Control VCA IgG and the modified device, LIAISON® VCA IgG Serum Control Set.

Summary of Similarities and Differences LIAISON® VCA IgG Control Set		
Characteristic	**Predicate Device DiaSorin LIAISON® Control VCA IgG K040120, Cleared 06/01/2005**	**Modified Device DiaSorin LIAISON® VCA IgG Serum Control Set**
Intended Use	The LIAISON® VCA IgG Controls (negative, positive) are used for monitoring substantial reagent failure of the LIAISON® VCA IgG chemiluminescent immunoassay (CLIA). The LIAISON® VCA IgG quality control material contains a 5% serum matrix and may not adequately control the DiaSorin LIAISON® VCA IgG assay for serum specimens. The performance of the LIAISON® VCA IgG Controls has not been established with any other EBV assay or instrument platforms different from LIAISON® and LIAISON® XL.	The DiaSorin LIAISON® VCA IgG Serum Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® VCA IgG assay on the LIAISON® Analyzer family*. The performance characteristics of the LIAISON® VCA IgG controls have not been established for any other assay or instrument platforms different from the LIAISON® and LIAISON® XL. *(LIAISON® and LIAISON® XL).
Negative Control	5% Human serum/defibrinated plasma not reactive for VCA IgG antibodies, diluted in PBS buffer, BSA, with ProClin® 300 as a preservative.	Human serum/defibrinatedplasma non-reactive for VCA IgG antibodies, 0.1% ProClin® 300 and 0.09% sodium azide.
Positive Control	5% Human serum/defibrinated plasma reactive for VCA IgG antibodies, diluted in PBS buffer, BSA, with ProClin® 300 as a preservative and an inert yellow dye.	Human serum/defibrinated plasma reactive for VCA IgG antibodies, 0.1% ProClin® 300 and 0.09% sodium azide.
Reagent Configuration	2 vials each level (negative and positive) 0.9 mL/vial, ready to use.	Same
Storage	Store at 2-8ºC	Same
Open Use Stability	Once opened controls are stable for four (4) weeks when properly stored at 2-8ºC between uses.	Once opened controls are stable for eight (8) weeks when properly stored at 2-8ºC between uses.

ProClin® is a trademark of the Dow Chemical Company (Dow) or an affiliated company of Dow.

SUMMARY OF PERFORMANCE DATA:

Non-clinical verification and validation testing conducted with the LIAISON® VCA IgG and LIAISON® VCA IgG Serum Control Set demonstrate that the modified device meets predetermined acceptance criteria, supporting equivalency of the modified device to the cleared device. Evidence is demonstrated through the following studies:

Testing of the LIAISON® VCA IgG Serum Control Set to validate and verify:

- Commutability between samples and controls (matrix effect)
- Precison equivalence between samples and controls
    - 20 day precison
- Control value assignment
- Control range definition

Real Time Stability testing conducted on the LIAISON® VCA IgG Serum Control Set to support the following product claims:

- Shelf-life of 12 months at (2-8°C)
- Eight (8) weeks open use stability when stored at 2-8°C between uses

Based on the results from the validation and verification activities, the modifications to the LIAISON® VCA IgG Serum Control Set do not introduce any new risks to the performance of the device.

CONCLUSION:

As summarized, LIAISON® VCA IgG and LIAISON® VCA IgG Serum Control Set is substantially equivalent to the originally cleared device. The changes to the device do not constitute new intended/indications for use, or changes to the fundamental scientific technology. Performance testing of the device demonstrates that the device functions as intended, meeting the requirements of design specifications. The device was determined to be substantially equivalent to the previously cleared device.

The material submitted in this Special 510(k) is complete and supports a substantial equivalence decision. The labeling satisfies the requirements of 21 CFR 809.10.

510(k) SUMMARY

SUBMITTED BY:
DiaSorin Inc.
1951 Northwestern Avenue
P.O. Box 285
Stillwater, MN 55082-0285

CONTACT:
Gagan Gill
Regulatory Affairs Associate
Email: gagan.gill@diasorin.com

DATE OF PREPARATION: October 21, 2016

NAME OF DEVICE:

Trade Name: LIAISON® EBNA IgG
LIAISON® EBNA IgG Serum Control Set

Common Names/Description: Immunoassay for the detection of IgG antibodies to EBV Nuclear Antigen (EBNA)

Classification: Epstein-Barr Virus, serological reagents; 21 CFR 866.3235; Class I, Microbiology(83)

Product Code: LLM, JJX

PREDICATE DEVICE: DiaSorin LIAISON® EBNA IgG (K040120)

DEVICE DESCRIPTION:
The LIAISON® EBNA IgG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® Analyzer family for the qualitative determination of specific IgG antibodies to Epstein-Barr virus (EBV) nuclear antigen synthetic peptide (EBNA-1) in human serum.

The LIAISON® EBNA IgG Serum Control Set (negative and positive) consists of liquid ready-to-use controls in human serum. The negative control is intended to provide an assay response characteristic of negative patient specimens and the positive control is intended to provide an assay response characteristic of positive patient specimens.

The controls are designed for use with DiaSorin LIAISON® EBNA IgG assay on the LIAISON® Analyzer family.

INTENDED USE:
The LIAISON® EBNA IgG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® Analyzer family* for the qualitative determination of specific IgG antibodies to Epstein-Barr virus (EBV) nuclear antigen synthetic peptide (EBNA-1) in human serum. When performed in conjunction with other EBV markers, this assay can be used as an aid in the clinincal laboratory diagnosis of Epstein-Barr Viral Syndrome in patients with signs and symptoms of EBV infection such as infectious mononucleosis.

The DiaSorin LIAISON® EBNA IgG Serum Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® EBNA IgG assay on the LIAISON® Analyzer family*. The performance characteristics of the LIAISON® EBNA IgG controls have not

been established for any other assay or instrument platforms different from the LIAISON® and LIAISON® XL.

*(LIAISON® and LIAISON® XL)

COMPARISON TO THE PREDICATE (Description of the Modifications to the Legally Marketed Device):

The following table provides a summary of the FDA cleared LIAISON® EBNA IgG assay.

LIAISON® EBNA IgG assay		
Characteristic	**Predicate Device DiaSorin LIAISON® EBNA IgG K040120, cleared 06/01/2005**	**DiaSorin LIAISON® EBNA IgG**
Intended Use/Indications for Use	The LIAISON® EBNA IgG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® Analyzer family* for the qualitative determination of specific IgG antibodies to Epstein-Barr virus (EBV) nuclear antigen synthetic peptide (EBNA-1) in human serum. When performed in conjunction with other EBV markers, this assay can be used as an aid in the clinincal laboratory diagnosis of Epstein-Barr Viral Syndrome in patients with signs and symptoms of EBV infection such as infectious mononucleosis. *(LIAISON® and LIAISON® XL).	No Change
Technology/ Assay Principle	Chemiluminescent Immunoassay (CLIA)	No Change
Sample Handling/Assay Processing	Automated	No Change
Storage	Store at 2-8º C until ready to use	No Change
Measured Analyte	IgG antibodies to Epstein-Barr virus (EBV) nuclear antigen	No Change
Assay Performance Characteristics	No Change	No Change
Labeling (IFU)	References buffer based controls	References serum based controls
Controls	Provided Separately	No Change

Changes to the DiaSorin LIAISON® EBNA IgG Serum Control Set include a 100% serum/defibrinated plasma based matrix and the extension of the open use stability claim.

The following table provides a summary of the similarities and differences between the FDA cleared LIAISON® Control EBNA IgG and the modified device, LIAISON® EBNA IgG Serum Control Set.

Summary of Similarities and Differences LIAISON® EBNA IgG Control Set		
Characteristic	**Predicate Device DiaSorin LIAISON® Control EBNA IgG K040120, cleared 06/01/2005**	**Modified Device DiaSorin LIAISON® EBNA IgG Serum Control Set**
Intended Use	The LIAISON® EBNA IgG Serum Controls (negative, positive) are used for monitoring substantial reagent failure of the LIAISON® EBNA IgG chemiluminescent immunoassay (CLIA). The LIAISON® EBNA IgG quality control material contains a 5% serum matrix and may not adequately control the DiaSorin LIAISON® EBNA IgG assay for serum specimens. The performance of the LIAISON® EBNA IgG Controls has not been established with any other EBV assay or instrument platforms different from LIAISON® and LIAISON® XL.	The DiaSorin LIAISON® EBNA IgG Serum Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® EBNA IgG assay on the LIAISON® Analyzer family*. The performance characteristics of the LIAISON® EBNA IgG controls have not been established for any other assay or instrument platforms different from the LIAISON® and LIAISON® XL. *(LIAISON® and LIAISON® XL).
Negative Control	5% Human serum/ defibrinated plasma not reactive for EBNA IgG antibodies, diluted in PBS buffer, BSA, with ProClin® 300 as a preservative.	Human serum/defibrinated plasma non-reactive for EBNA IgG antibodies, 0.1% ProClin® 300 and 0.09% sodium azide.
Positive Control	5% Human serum/defibrinated plasma reactive for EBNA IgG antibodies, diluted in PBS buffer, BSA, with ProClin® 300 as a preservative and an inert yellow dye.	Human Serum/defibrinated plasma reactive for EBNA IgG antibodies, 0.1% ProClin® 300 and 0.09% sodium azide.
Reagent Configuration	2 vials each level (negative and positive) 0.9 mL/vial, ready to use.	Same
Storage	Store at 2-8ºC	Same
Open Use Stability	Once opened controls are stable for four (4) weeks when properly stored at 2-8ºC between uses.	Once opened controls are stable for eight (8) weeks when properly stored at 2-8ºC between uses.

ProClin® is a trademark of the Dow Chemical Company (Dow) or an affiliated company of Dow.

SUMMARY OF PERFORMANCE DATA:

Non-clinical verification and validation testing conducted with the LIAISON® EBNA IgG and LIAISON® EBNA IgG Serum Control Set demonstrate that the modified device meets predetermined acceptance criteria, supporting equivalency of the modified device to the cleared device. Evidence is demonstrated through the following studies:

Testing of the LIAISON® EBNA IgG Serum Control Set to validate and verify:

- Commutability between samples and controls (Matrix Effect)
- Precison equivalence between samples and controls
    - 20 Day Precison
- Control value assignment
- Control range definition

Real time stability testing conducted on the LIAISON® EBNA IgG Serum Control Set to support the following product claims:

- Shelf-life of 12 months at (2-8°C)
- Eight (8) weeks open use stability when stored at 2-8°C between uses

Based on the results from the validation and verification activities, the modifications to the LIAISON® EBNA IgG Serum Control Set do not introduce any new risks to the performance of the device.

CONCLUSION:

As summarized, LIAISON® EBNA IgG and LIAISON® EBNA IgG Serum Control Set is substantially equivalent to the originally cleared device. The changes to the device do not constitute new intended/indications for use, or changes to the fundamental scientific technology. Performance testing of the device demonstrates that the device functions as intended, meeting the requirements of design specifications. The device was determined to be substantially equivalent to the previously cleared device.

The material submitted in this Special 510(k) is complete and supports a substantial equivalence decision. The labeling satisfies the requirements of 21 CFR 809.10.