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

DiaSorin Inc.
Sandra Zimniewicz
Regulatory Affairs Specialist
1951 Northwestern Avenue
Stillwater, MN 55082

June 30, 2016

Re: K161526
Trade/Device Name: LIAISON® CMV IgM Serum Control Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed).
Regulatory Class: I
Product Code: JJX
Dated: May 31, 2016
Received: June 02, 2016

Dear Ms. Zimniewicz:

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,

Stephen J. Lovell -S for

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostics and
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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)*

Device Name
LIAISON® CMV IgM Serum Control Set

Indications for Use *(Describe)*
The LIAISON® CMV IgM Serum Control Set (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® CMV IgM assay on the LIAISON® Analyzer family.

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.

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7.0 510(k) SUMMARY

SUBMITTED BY: Sandra Zimniewicz
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DATE PREPARED: May 31, 2016

NAME OF DEVICE:

Trade Name:	LIAISON® CMV IgM Serum Control Set
Common Names/Description:	CMV IgM Controls
Classification:	Quality Control Material: 21 CFR 862.1660; Class I, reserved; Microbiology (83)
Product Code:	JJX

PREDICATE DEVICE: LIAISON® Control CMV IgM (K040290)

DEVICE DESCRIPTION:
The LIAISON® CMV IgM 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® CMV IgM assay on the LIAISON® analyzer family.

INTENDED USE:
The LIAISON® CMV IgM Serum Control Set (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® CMV IgM assay on the LIAISON® Analyzer family.

COMPARISON TO THE PREDICATE (Description of the Modifications to the Legally Marketed Device):
Changes to the DiaSorin LIAISON® CMV IgM 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 CMV IgM and the modified device.

Summary of Similarities and Differences LIAISON® CMV IgM Controls		
Characteristic	**Predicate Device LIAISON® Control CMV IgM k040290, cleared 06/01/2005**	**Modified Device LIAISON® CMV IgM Serum Control Set**
Intended Use	The LIAISON® CMV IgM controls (negative and positive) are used for monitoring substantial reagent failure of the LIAISON® CMV IgM chemiluminescent immunoassay (CLIA). The LIAISON® CMV IgM quality control material contains only a 5% serum matrix and may not adequately control the DiaSorin LIAISON® CMV IgM assay for serum specimens.	The LIAISON® CMV IgM Serum Controls (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® CMV IgM assay on the LIAISON® Analyzer family.
Negative Control	5% Human Serum/plasma not reactive for CMV IgM antibodies, diluted in PBS buffer, BSA, with ProClin® 300 as a preservative.	Human Serum/plasma non-reactive for CMV IgM antibodies, 0.1% ProClin® 300 and 0.09% sodium azide.
Positive Control	5% Human Serum/plasma reactive for CMV IgM antibodies, diluted in PBS buffer, BSA, with ProClin® 300 as a preservative and an inert yellow dye.	Human Serum/plasma reactive for CMV IgM antibodies, 0.1% ProClin® 300 and 0.09% sodium azide.
Reagent Configuration	2 vials each level (negative and positive) 0.7 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 sixteen (16) weeks when properly stored at 2-8ºC between uses.

SUMMARY OF PERFORMANCE DATA:

Non-clinical verification and validation testing conducted with the LIAISON® CMV IgM 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:

- Commutability between Samples and Controls (Matrix Effect)
- Precision Equivalence between Samples and Controls
- Control Value Assignment
- Control Range Definition

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

- Shelf-life of 12 months at (2-8°C)
- Sixteen(16) weeks On-Board/Open Use Stability

Based on the findings from the validation and verification activities, the modifications to the LIAISON® CMV IgM Serum Control Set do not introduce any new risks to the performance of the device and do not alter safety and effectiveness.

CONCLUSION:
Modifications 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 is as safe and effective as the predicate and does not raise new questions of safety and efficacy.

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.