SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE **RE:** DOCUMENT NUMBER K162969

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I device requiring 510(k). The following items are present and acceptable:

1. The name and 510(k) number of the SUBMITTER'S previously cleared device:

   DiaSorin LIAISON® CMV IgG

   510(k) number: K040290

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, and package labeling.

   The intended use of the DiaSorin LIAISON® CMV IgG assay did not change. The intended use of the Controls (required for the assay and sold separately) was updated to reflect the change in the Control matrix.

3. A description of the device **MODIFICATIONS** in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

   A. Changes to the DiaSorin LIAISON® CMV IgG assay:

      1. The Quality Control section of the package insert was updated to reflect the change in the Control matrix.

   B. Changes to the LIAISON® Control CMV IgG:

      1. The name is changed to LIAISON® CMV IgG Serum Control Set.
      2. The Positive and Negative Controls included in the LIAISON® CMV IgG Serum Control Set are provided in a matrix of 100% human serum/defibrinated plasma instead of in a matrix comprised of buffer and 5% human serum/defibrinated plasma.
      3. The Open Use stability claim of the LIAISON® CMV IgG Serum Control Set is extended from 4 weeks to 8 weeks when stored at 2 – 8°C. The storage condition of the Controls did not change.

4. **Comparison Information**

LIAISON® CMV IgG assay		
	Predicate Device DiaSorin LIAISON® CMV IgG, K040290, Cleared 06/01/2005	**Modified Device LIAISON® CMV IgG and LIAISON® CMV IgG Serum Control Set**
Intended Use/Indications for Use	The LIAISON® CMV IgG assay uses chemiluminescent immunoassay (CLIA) technology on the LIAISON® Analyzer family* for the qualitative determination of IgG antibodies to human cytomegalovirus (hCMV) in human serum. It is intended to be used as an aid in the determination of serological status to CMV. *(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 human cytomegalovirus (hCMV)	No Change
Assay Performance Characteristics	No Change	No Change
Labeling (Instructions for Use)	References buffer based controls	References serum based controls
Controls	Provided Separately	No Change

LIAISON® CMV IgG Serum Control Set		
	Predicate Device DiaSorin LIAISON® CMV IgG, K040290, Cleared 06/01/2005	**Modified Device LIAISON® CMV IgG and LIAISON® CMV IgG Serum Control Set**
Intended Use	The LIAISON® CMV IgG Controls (negative, positive) are used for monitoring substantial reagent failure of the LIAISON® CMV IgG chemiluminescent immunoassay (CLIA). The LIAISON® CMV IgG quality control material contains only a 5% serum matrix and may not adequately control the DiaSorin LIAISON® CMV IgG assay for serum specimens. The performance of the LIAISON® CMV IgG Controls has not been established with any other CMV assay or instrument platforms different from LIAISON® and LIAISON® XL.	The DiaSorin LIAISON® CMV IgG Serum Control Set is intended for use as assayed quality control samples to monitor the performance of the LIAISON® CMV IgG assay on the LIAISON® Analyzer family*. The performance characteristics of the LIAISON® CMV 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 non-reactive for CMV IgG antibodies, diluted in PBS buffer, BSA, with ProClin® 300 as a preservative.	Human serum/defibrinated plasma non-reactive for CMV IgG antibodies, 0.1% ProClin® 300 and 0.09% sodium azide.
Positive Control	5% Human serum/defibrinated plasma reactive for CMV IgG antibodies, diluted in PBS buffer, BSA, with ProClin® 300 as a preservative and an inert yellow dye.	Human serum/defibrinated plasma reactive for CMV IgG 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.	No change
Storage	Store at 2 – 8°C	No change
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.

5. A **Design Control Activities Summary** which includes:

   a) Identification of Risk Analysis method used to assess the impact of the modification on the device and its components, and the results of the analysis.

   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

      Stability studies on the modified Controls were performed. Precision and matrix effect studies were also performed.

   c) A "Declaration of Conformity" statement was also submitted for the manufacturing facility and validation activities and signed by the Senior Director Regulatory Affairs and Quality Assurance. The statements indicate that:

      I. The manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
      II. The validation activities, as required by the risk analysis, for the modification were performed by the designated individuals and the results demonstrated that the predetermined acceptance criteria were met.

The labeling for these modified subject devices has been reviewed to verify that the indication/intended use for the device, the LIAISON® CMV IgG assay, is unaffected by the modification. The intended use of the component, the LIAISON® CMV IgG Serum Control Set, was updated to reflect the change in composition of the Control matrix. In addition, the submitter's description of the particular modifications and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared device.