

SPECIAL 510(k): Device Modification
OIR Decision Summary

To: THE FILE

RE: DOCUMENT NUMBER K161522

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own 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.

Trade Name: LIAISON® Control EBV IgM 510(k) number: K040120

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.
3. A description of the device **MODIFICATIONS**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

This change was for: Modifications to the LIAISON® EBV IgM Control Set consisting of a change from a buffer to a human serum matrix and extension of the open use stability claim.

4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, and physical characteristics is shown in the table below.

Summary of Similarities and Differences: LIAISON® EBV IgM Control Set		
Characteristic	Predicate Device DiaSorin LIAISON® Control EBV IgM (K040120)	Modified Device DiaSorin LIAISON® EBV IgM Serum Control Set (K161522)
Intended Use	The LIAISON® EBV IgM controls (negative and positive) are used for monitoring substantial reagent failure of the LIAISON® EBV IgM chemiluminescent immunoassay (CLIA). The LIAISON® EBV IgM quality control material contains only a 5% serum matrix and may not adequately control the DiaSorin LIAISON® EBV IgM assay for serum specimens.	The LIAISON® EBV IgM Serum Control Set (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the LIAISON® EBV IgM assay on the LIAISON® Analyzer family.
Negative Control	5% Human Serum/plasma not reactive for VCA IgM antibodies, diluted in PBS buffer, BSA, with ProClin® 300 as a preservative.	Human Serum/plasma non-reactive for VCA IgM antibodies, 0.1% ProClin® 300 and 0.09% sodium azide.

Summary of Similarities and Differences: LIAISON® EBV IgM Control Set		
Characteristic	Predicate Device DiaSorin LIAISON® Control EBV IgM (K040120)	Modified Device DiaSorin LIAISON® EBV IgM Serum Control Set (K161522)
Positive Control	5% Human Serum/plasma reactive for VCA IgM antibodies, diluted in PBS buffer, BSA, with ProClin® 300 as a preservative and an inert yellow dye.	Human Serum/plasma reactive for VCA IgM 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 2-8°C	Same
Open Use Stability	Once opened, controls are stable for four (4) weeks when properly stored at 2-8°C between uses.	Once opened, controls are stable for sixteen (16) weeks when properly stored at 2-8°C between uses.

5. A **Design Control Activities Summary** which includes:
- a) Identification of Risk Analysis method(s) 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

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. 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.