

## **SPECIAL 510(k): Device Modification OIR Decision Summary**

**To:** THE FILE

**RE:** DOCUMENT NUMBER K150375

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

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

LIAISON<sup>®</sup> VZV IgG and LIAISON<sup>®</sup> Control VZV IgG

510(k) number: K061820

2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED**. There are changes in labeling which are described below.
3. A description of the device **MODIFICATION(S)**, in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed**.

**The changes were for:**

A. Changes to the LIAISON VZV IgG:

1. Increase in number of tests per kit from 50 to 100 tests.
2. Extension of On-Board and Open Use stability claim for the Reagent Integral from four weeks to eight weeks when stored at 2-8°C in a refrigerator or on board the analyzer.
3. Calibration stability extension from two weeks to eight weeks.
4. Extend refrigerated storage (2-8°C) for specimens from two days to seven days.
5. Addition of specimen stability claim that allows samples to undergo five freeze-thaw cycles.
6. Changes to the Quality Control recommendations to reflect the change in the matrix composition of the LIAISON<sup>®</sup> Control VZV IgG.

B. Changes to the LIAISON<sup>®</sup> Control VZV IgG:

1. Controls (Positive and Negative) to be provided in a serum based matrix (100% human serum).
2. Extension of On-Board and Open Use stability claim for controls from four weeks to eight weeks when stored at 2-8°C.
3. Addition of a description of Assigned Values of the controls and the procedure for using the controls.

## 4. Comparison Information

<b>Similarities LIAISON<sup>®</sup> VZV IgG</b>		
<b>Characteristic</b>	<b>Predicate Device DiaSorin LIAISON<sup>®</sup> VZV IgG K061820, cleared 02/26/2007</b>	<b>Modified Device DiaSorin LIAISON<sup>®</sup> VZV IgG</b>
Intended Use/Indications for Use	The DiaSorin LIAISON <sup>®</sup> VZV IgG uses chemiluminescence immunoassay (CLIA) technology on the LIAISON <sup>®</sup> Analyzer family for the qualitative detection of specific IgG antibodies to varicella-zoster virus (VZV) in human serum. This assay can be used as an aid in the determination of previous infection of varicella-zoster virus. The assay performance in detecting antibodies to VZV in individuals vaccinated with the FDA- licensed VZV vaccine is unknown. The user of this assay is responsible for establishing the performance characteristics with VZV vaccinated individuals.	Same
Technology/ Assay Principle	Chemiluminescent Immunoassay (CLIA)	Same
Sample Handling/Assay Processing	Automated	Same
Reagent Integral Configuration (1 compartment each reagent)	<ul style="list-style-type: none"> <li>• Magnetic particles</li> <li>• Calibrator 1</li> <li>• Calibrator 2</li> <li>• Specimen Diluent</li> <li>• Conjugate</li> </ul>	Same
Raw Materials	No Change <ul style="list-style-type: none"> <li>• Antigen: Inactivated varicella-zoster virus lysate (ROD strain)</li> <li>• Detector: Mouse monoclonal anti-human IgG conjugated to isoluminol derivative</li> <li>• Capture: Magnetic microparticles coated with varicella-zoster antigen</li> </ul>	Same
Reagent Formulation	No Change	Same
Manufacturing Process	No Change	Same
Storage	Store at 2-8°C until ready to use	Same

<b>Similarities LIAISON<sup>®</sup> VZV IgG</b>		
<b>Characteristic</b>	<b>Predicate Device DiaSorin LIAISON<sup>®</sup> VZV IgG K061820, cleared 02/26/2007</b>	<b>Modified Device DiaSorin LIAISON<sup>®</sup> VZV IgG</b>
Measured Analyte	IgG antibodies to Varicella-zoster virus	Same
Sample Type	Human Serum	Same
Sample Volume	20 uL	Same
Assay Procedure	<ul style="list-style-type: none"> <li>• Dispense calibrators, controls, or samples</li> <li>• Dispense magnetic particles</li> <li>• Dispense specimen diluent</li> <li>• Incubate</li> <li>• Wash</li> <li>• Dispense conjugate</li> <li>• Incubate</li> <li>• Wash</li> <li>• Dispense starter reagent</li> <li>Measure Light emitted (RLUs)</li> </ul>	Same
Total Incubation Time	21 minutes	Same
Measurement System	Photomultiplier (flash chemiluminescence reader)	Same
Calibration	Two point verification of stored master curve	Same
Unit of Measure	Index Value	Same
Cut-Off	150 Index Value	Same
Equivocal Zone	135 – 165 Index Value	Same
Calibrators	Included with kit	Same
Assay Performance Characteristics	No Change	Same
Controls	Provided Separately	Same

<b>Differences LIAISON<sup>®</sup> VZV IgG</b>		
<b>Characteristic</b>	<b>Predicate Device DiaSorin LIAISON<sup>®</sup> VZV IgG K061820, cleared 02/26/2007</b>	<b>Modified Device DiaSorin LIAISON<sup>®</sup> VZV IgG</b>
Tests per Kit	50	100
Reagent Volume	Magnetic particles (1.3ml) Conjugate (13ml)	Magnetic particles (2.5 ml) Conjugate (23ml)
Open Use/On Board Stability	Four (4) weeks at 2-8°C or on board the analyzer	Eight (8) weeks at 2-8°C or onboard the analyzer
Calibration Stability	Fourteen (14) days	Eight (8) weeks
Serum Storage at	Two (2) days	Seven (7) days
Serum Storage Freeze-Thaw Cycles	Samples should not be repeatedly frozen and thawed.	Samples are stable through five (5) freeze-thaw cycles.

<b>Similarities LIAISON<sup>®</sup> Control VZV IgG</b>		
<b>Characteristic</b>	<b>Predicate Device DiaSorin LIAISON<sup>®</sup> VZV IgG K061820, cleared 02/26/2007</b>	<b>Modified Device DiaSorin LIAISON<sup>®</sup> VZV IgG</b>
Intended Use	The LIAISON <sup>®</sup> VZV IgG controls (negative, positive controls) are used for monitoring substantial reagent failure of the LIAISON <sup>®</sup> VZV IgG chemiluminescent immunoassay (CLIA). The LIAISON <sup>®</sup> VZV IgG quality control material contains a 5% serum matrix and may not adequately control the DiaSorin LIAISON <sup>®</sup> VZV IgG assay for serum specimens. The performance of the LIAISON <sup>®</sup> VZV IgG controls has not been established with any other VZV assay or instrument platforms different from LIAISON <sup>®</sup> and LIAISON <sup>®</sup> XL.	The DiaSorin LIAISON <sup>®</sup> Control VZV IgG (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the DiaSorin LIAISON <sup>®</sup> VZV IgG assay on the LIAISON <sup>®</sup> Analyzer family. The performance characteristics of the LIAISON <sup>®</sup> VZV Control IgG have not been established for any other assay or instrument platforms different from LIAISON <sup>®</sup> and LIAISON <sup>®</sup> XL.
Reagent Configuration	2 vials each level (negative and positive) 0.7 mL/vial, ready to use.	Same
Storage	Store at 2-8° C until ready to use.	Same

<b>Differences LIAISON<sup>®</sup> Control VZV IgG</b>		
<b>Characteristic</b>	<b>Predicate Device DiaSorin LIAISON<sup>®</sup> VZV IgG K061820, cleared 02/26/2007</b>	<b>Modified Device DiaSorin LIAISON<sup>®</sup> VZV IgG</b>
Negative Control	5% Human Serum non-reactive for VZV IgG antibodies, stabilized in TRIS-NaCl buffer, preservatives.	Human Serum non-reactive for VZV IgG antibodies, 0.2% ProClin.
Positive Control	5% Human Serum/plasma reactive for VZV IgG antibodies, stabilized in TRIS-NaCl buffer, preservatives, inert yellow dye.	Human Serum reactive for VZV IgG antibodies, 0.2% ProClin.
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 eight (8) 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. Stability studies on reagents, calibrators, controls and serum were carried out. 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 Quality Assurance and Regulatory Affairs Manager, Italy. 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 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 modification(s) 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 (or their preamendment) device.