**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

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

March 11, 2015

Re: K150375
Trade/Device Name: LIAISON® VZV IgG and LIAISON® Control VZV IgG
Regulation Number: 21 CFR 866.3900
Regulation Name: Varicella-zoster virus serological reagents
Regulatory Class: Class II
Product Code: LFY, JJX
Dated: February 12, 2015
Received: February 13, 2015

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 Part 801); 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,

Stephen J. Lovell -S for

Sally Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
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)*
K150375

Device Name
LIAISON® VZV IgG
LIAISON® Control VZV IgG

Indications for Use *(Describe)*
The DiaSorin LIAISON® VZV IgG uses chemiluminescence immunoassay (CLIA) technology on the LIAISON® 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.

The DiaSorin LIAISON® Control VZV IgG (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the DiaSorin LIAISON® VZV IgG assay on the LIAISON® Analyzer family. The performance characteristics of the LIAISON® Control VZV IgG have not been established for any other assays or instrument platforms different from 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.

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# 510(k) SUMMARY

SUBMITTED BY:

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DATE PREPARED: February 12, 2015

NAME OF DEVICE:

| | |
|---|---|
| Trade Name: | LIAISON® VZV IgG<br>LIAISON® Control VZV IgG |
| Common Names/Description: | VZV IgG Assay and VZV IgG Controls |
| Classification: | Varicella-zoster virus Serological Reagents: 21 CFR 866.3900; Class II (performance standards); Microbiology (83) |
| Product Code: | LFY, JJX |

PREDICATE DEVICE: LIAISON® VZV IgG (k061820)

DEVICE DESCRIPTION:
The LIAISON® VZV IgG is an indirect chemiluminescence immunoassay (CLIA) for qualitative determination of specific IgG antibodies to varicella-zoster virus in human serum.

The LIAISON® Control VZV IgG are liquid ready-to-use controls based 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 assay and controls are designed for use with DiaSorin LIAISON® Analyzer family.

INTENDED USE:
The DiaSorin LIAISON® VZV IgG uses chemiluminescence immunoassay (CLIA) technology on the LIAISON® Analyzer family for the qualitative detection of specific IgG

antibodies to varicella-zoster (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.

The DiaSorin LIAISON® Control VZV IgG (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the DiaSorin LIAISON® VZV IgG assay on the LIAISON® Analyzer family. The performance characteristics of the LIAISON® Control VZV IgG have not been established for any other assay or instrument platforms different from LIAISON® and LIAISON® XL.

COMPARISON TO THE PREDICATE (Description of the Modifications to the Legally Marketed Device):
Modifications to the DiaSorin LIAISON® VZV IgG assay include an increase in the number of tests provided per kit, extension of on board/open use and calibration stability, the addition of serum specimen stability claim for 5 freeze-thaw cycles and the extension of refrigerated storage (2-8ºC) for serum specimens from two (2) days to seven (7) days.

Changes to the DiaSorin LIAISON® Control VZV IgG 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® VZV IgG, LIAISON® Control VZV IgG and the modified devices.

| **Table of Similarities LIAISON® VZV IgG** | | |
|---|---|---|
| **Characteristic** | **Predicate Device DiaSorin LIAISON® VZV IgG k061820, cleared 02/26/2007** | **Modified Device DiaSorin LIAISON® VZV IgG** |
| Intended Use/Indications for Use | The DiaSorin LIAISON® VZV IgG uses chemiluminescence immunoassay (CLIA) technology on the LIAISON® 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.<br>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<br>(1 compartment each reagent) | • Magnetic particles<br>• Calibrator 1<br>• Calibrator 2<br>• Specimen Diluent<br>• Conjugate | Same |
| Raw materials | No Change<br>• Antigen: Inactivated varicella-zoster virus lysate (ROD strain)<br>• Detector: Mouse monoclonal anti-human IgG conjugated to isoluminol derivative<br>• Capture: Magnetic microparticles coated with varicella-zoster antigen | Same |
| Reagent Formulation | No Change | Same |
| Manufacturing Process | No Change | Same |
| Storage | Store at 2-8ºC until ready to use | Same |
| Measured Analyte | IgG antibodies to Varicella-zoster virus | Same |
| Sample Type | Human Serum | Same |
| Sample Volume | 20 uL | Same |
| Assay Procedure | • Dispense calibrators, controls, or samples<br>• Dispense magnetic particles<br>• Dispense specimen diluent<br>• Incubate<br>• Wash<br>• Dispense conjugate<br>• Incubate<br>• Wash<br>• Dispense starter reagent<br>• Measure Light emitted (RLUs) | 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 |

| **Table of Differences LIAISON® VZV IgG** | | |
|---|---|---|
| **Characteristic** | **Predicate Device DiaSorin LIAISON® VZV IgG k061820, cleared 02/26/2007** | **Modified Device DiaSorin LIAISON® VZV IgG** |
| Tests per Kit | 50 | 100 |
| Reagent Volume Provided | Magnetic particles (1.3ml)<br>Conjugate (13ml) | Magnetic particles (2.5 ml)<br>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 2-8°C | Two (2) days | Seven (7) days |
| Serum Storage Freeze-Thaw Cycles | Samples should not be repeatedly frozen and thawed. | Twelve samples with different reactivity underwent five (5) freeze-thaw cycles. The results showed no significant differences. |

| **Summary of Similarities and Differences LIAISON® Control VZV IgG** | | |
|---|---|---|
| **Characteristic** | **Predicate Device DiaSorin LIAISON® Control VZV IgG k061820, cleared 02/26/2007** | **Modified Device DiaSorin LIAISON® Control VZV IgG** |
| Intended Use | The LIAISON® VZV IgG controls (negative, positive controls) are used for monitoring substantial reagent failure of the LIAISON® VZV IgG chemiluminescent immunoassay (CLIA). The LIAISON® VZV IgG quality control material contains a 5% serum matrix and may not adequately control the DiaSorin LIAISON® VZV IgG assay for serum specimens. The performance of the LIAISON® VZV IgG controls has not been established with any other VZV assay or instrument platforms different from LIAISON® and LIAISON® XL. | The DiaSorin LIAISON® Control VZV IgG (negative and positive) is intended for use as assayed quality control samples to monitor the performance of the DiaSorin LIAISON® VZV IgG assay on the LIAISON® Analyzer family. The performance characteristics of the LIAISON® VZV Control IgG have not been established for any other assay or instrument platforms different from LIAISON® and LIAISON® XL. |
| Negative Control | 5% Human Serum/plasma non-reactive for VZV IgG antibodies, stabilized in TRIS-NaCl buffer, preservatives. | Human Serum/plasma 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/plasma reactive for VZV IgG antibodies, 0.2% ProClin. |
| Reagent Configuration | 2 vials each level (negative and positive) 0.7 mL/vial, ready to use. | Same |
| Storage | Store at 2-8ºC until ready to use | 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. |

SUMMARY OF PERFORMANCE DATA:

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

Real Time Stability testing conducted on the LIAISON® VZV IgG to support the following product claims:

- Eight (8) weeks On-Board/Open Use Stability
- Eight (8) weeks Stability of Calibration

Real time stability testing on human serum specimens to support storage claims:

- Seven (7) Days Refrigerated (2-8°C)
- Five (5) Freeze-Thaw Cycles

Testing of the LIAISON® Control VZV IgG to validate and verify:

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

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

- Shelf-life of 18 months at (2-8°C)
- Eight (8) weeks On-Board/Open Use Stability

Based on the findings from the validation and verification activities, the modifications to the LIAISON® VZV IgG and LIAISON® Control VZV lgG do not introduce any new risks to the performance of the device.

CONCLUSION:

As summarized, the DiaSorin LIAISON® VZV IgG and LIAISON® Control VZV IgG, are substantially equivalent to the originally cleared devices. 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.