October 27, 2023

DiaSorin Inc.
Kelly Olien
Regulatory Affairs Specialist II
1952 Northwestern Avenue
Stillwater, Minnesota 55082

Re: K231214
Trade/Device Name: LIAISON VZV IgG HT, LIAISON Control VZV IgG HT
Regulation Number: 21 CFR 866.3900
Regulation Name: Varicella-zoster virus serological reagents
Regulatory Class: Class II
Product Code: LFY
Dated: September 29, 2023
Received: September 29, 2023

Dear Kelly Olien:

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laura E. Ulitzky -S

Digitally signed by Laura E. Ulitzky -S
Date: 2023.10.27 12:17:29 -04'00'

Laura Ulitzky
Lead Biologist
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231214

Device Name
LIAISON VZV IgG HT, LIAISON Control VZV IgG HT

Indications for Use *(Describe)*
The LIAISON VZV IgG HT assay uses chemiluminescent immunoassay (CLIA) technology for the in vitro qualitative detection of specific IgG antibodies to varicella-zoster virus (VZV) in human serum (with gel and without gel-SST), dipotassium EDTA (K2- EDTA), lithium heparin and sodium heparin plasma samples. This assay is intended as an aid in the determination of previous infection of varicella-zoster virus. The test must be performed on the LIAISON XL Analyzer. 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.

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.

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510(k) SUMMARY

SUBMITTED BY:

Kelly Olien
Regulatory Affairs Specialist II
DiaSorin Inc.
1951 Northwestern Avenue
P.O. Box 285
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Email: kelly.olien@diasorin.com

DATE PREPARED: October 27, 2023

NAME OF DEVICE:

Trade Name:	LIAISON® VZV IgG HT, LIAISON® Control VZV IgG HT
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) Quality Control Material: 21 CFR 862.1660; Class I, reserved; Clinical Chemistry (75)
Product Code:	LFY

PREDICATE DEVICE: LIAISON® VZV IgG, LIAISON® Control VZV IgG (k150375)

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

The LIAISON® Control VZV IgG HT are liquid ready-to-use controls based in human serum and plasma. 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 LIAISON® VZV IgG HT assay uses chemiluminescent immunoassay (CLIA) technology for the in vitro qualitative detection of specific IgG antibodies to varicella-zoster virus (VZV) in human serum (with gel and without gel-SST), dipotassium EDTA (K2- EDTA), lithium heparin and sodium heparin plasma samples. This assay is intended as an aid in the determination of previous infection of varicella- zoster virus. The test must be performed on the LIAISON® XL Analyzer. 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.

COMPARISON TO THE PREDICATE The following tables provide a summary of the similarities and differences between the FDA cleared LIAISON® VZV IgG, and the new device.

Similarities		
Characteristic	**Predicate Device LIAISON® VZV IgG K150375**	**New Device LIAISON® VZV IgG HT K231214**
Technology/ Assay Principle	Chemiluminescent Immunoassay (CLIA)	Same
Sample Handling/Assay Processing	Automated	Same
Manufacturing Process	No Change	Same
Storage	Store at 2-8º C until ready to use	Same
Measured Analyte	IgG antibodies to Varicella-zoster virus	Same
Sample Volume	20 µL	Same
Assay Procedure	• Dispense calibrators, controls, or samples • Dispense magnetic particles • Dispense specimen diluent • Incubate • Wash • Dispense conjugate • Incubate • Wash • Dispense starter reagent • Measure Light emitted (RLUs)	Same
Measurement System	Photomultiplier (flash chemiluminescence reader)	Same
Calibrators	Included with kit	Same
Open Use/On Board Stability	Eight (8) weeks at 2-8°C or onboard the analyzer	Same
Calibration Stability	Eight (8) weeks	Same
Controls	Provided Separately	Same
Sample Storage at 2-8°C	Seven (7) days	Same
Serum Storage Freeze-Thaw Cycles	5 freeze-thaw cycles	Same

Differences		
Characteristic	**Predicate Device LIAISON® VZV IgG K150375**	**New Device LIAISON® VZV IgG HT K231214**
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. 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 LIAISON® VZV IgG HT assay uses chemiluminescent immunoassay (CLIA) technology for the in vitro qualitative detection of specific IgG antibodies to varicella-zoster virus (VZV) in human serum (with gel and without gel-SST), dipotassium EDTA (K2- EDTA), lithium heparin and sodium heparin plasma samples. This assay is intended as an aid in the determination of previous infection of varicella-zoster virus. The test must be performed on the LIAISON XL Analyzer. 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.
Reagent Integral Configuration (1 compartment each reagent)	• Magnetic particles • Calibrator 1 • Calibrator 2 • Specimen Diluent • Conjugate	• Magnetic particles • Calibrator • Assay Buffer • Conjugate
Raw materials	• Antigen: Inactivated varicella-zoster virus lysate (ROD strain) • Detector: Mouse monoclonal anti-human IgG conjugated to isoluminol derivative • Capture: Magnetic microparticles coated with varicella-zoster antigen	• Antigen: purified Varicella Zoster Virus glycoprotein; • Detector: same • Capture: Magnetic particles coated with varicella Zoster Virus glycoprotein
Sample Type	Human Serum	Human Serum and Plasma
Tests per Kit	100	200
Cut-Off	150 Index value	1.00 S/CO
Equivocal Zone	135 – 165 Index Value	No equivocal zone
Reagent Volume Provided	Magnetic particles (2.5 ml) Conjugate (23ml)	Magnetic particles (2.45 ml) Conjugate (28.5 ml)

Calibration	Two point verification of stored master curve	Calibration by using fully qualitative approach with one calibrator
Unit of Measure	Index Value	Signal/Cut-off (S/CO)

Summary of Similarities and Differences for the controls		
Characteristic	**Predicate Device LIAISON® Control VZV IgG K150375**	**New Device LIAISON® Control VZV IgG HT K231214**
Intended Use	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.	The LIAISON® Control VZV IgG HT (negative and positive) is intended for use as assayed quality control to monitor the performance and reliability of LIAISON® VZV IgG HT assay. The performance characteristics of LIAISON® Control VZV IgG HT have not been established for any other assays or instrument platforms different from the automated LIAISON® XL Analyzer.
Negative Control	Human Serum/plasma non-reactive for VZV IgG antibodies, 0.2% ProClin.	Human serum non-reactive for VZV IgG antibodies, 0.2% ProClin™ 300 and preservatives.
Positive Control	Human Serum/plasma reactive for VZV IgG antibodies, 0.2% ProClin.	Human serum / defibrinated plasma reactive for VZV IgG antibodies, 0.2% ProClin™ 300 and preservatives.
Reagent Configuration	2 vials each level (negative and positive) 0.7 mL/vial, ready to use.	Same
Storage	Store at 2-8º C until ready to use	Same
Open Use Stability	Once opened controls are stable for eight (8) weeks when properly stored at 2-8ºC between uses.	Same

SUMMARY OF PERFORMANCE DATA:

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

Clinical Agreement

A multisite clinical agreement study was conducted to evaluate the clinical performance of the LIAISON VZV IgG HT test. One thousand five hundred and forty four (1544) clinical human serum samples were used for this study, including 125 known positive specimens, 200 known negative specimens, 135 pregnant women specimens and 1084 specimens sent to the laboratory for testing.

The demography of the population tested is listed below:

Age Range	Gender	LIAISON VZV IgG HT				
		Positive Result		Negative Result		Total
		n	%	n	%	
0-9	F	1	16.7%	5	83.3%	6
	M	0	0.0%	4	100.0%	4
10-19	F	18	20.7%	69	79.3%	87
	M	4	18.2%	18	81.8%	22
	N*	1	33.3%	2	66.7%	3
20-29	F	223	37.0%	380	63.0%	603
	M	17	24.6%	52	75.4%	69
	N*	4	44.4%	5	55.6%	9
30-39	F	275	70.3%	116	29.7%	391
	M	34	70.8%	14	29.2%	48
	N*	1	25.0%	3	75.0%	4
40-49	F	88	73.9%	31	26.1%	119
	M	22	71.0%	9	29.0%	31
	N*	2	100.0%	0	0.0%	2
50-59	F	50	76.9%	15	23.1%	65
	M	25	65.8%	13	34.2%	38
	N*	2	100.0%	0	0.0%	2
60-69	F	19	86.4%	3	13.6%	22
	M	12	92.3%	1	7.7%	13
70-79	F	1	50.0%	1	50.0%	2
	M	0	0.0%	0	0.0%	0
80-89	F	1	50.0%	1	50.0%	2
	M	0	0.0%	0	0.0%	0
90-98	F	1	100.00%	0	0.0%	1
	M	0	0.0%	0	0.0%	0
Total (1543)**		**801**	**51.91%**	**742**	**48.1%**	**1543**

*N= Unknown

**one of the 1544 samples was excluded due to insufficient volume for testing on the candidate device

The samples were collected within the United States and tested at three independent external laboratories. Each sample, was tested with the LIAISON VZV IgG HT test and the comparator. The results for all populations are shown in the tables below.

The positive and negative percent agreements were calculated and presented below for normal laboratory routine (all), normal laboratory routine pediatric, and pregnant women. Specimens which were repeatedly equivocal by the predicate device were graded against the performance of the LIAISON® VZV IgG HT assay which does not have an equivocal zone.

Clinical Performance- Known Positive Specimens (n=125)

		FDA Cleared VZV IgG comparator			
		Positive	**Equivocal**	**Negative**	**Total**
LIAISON VZV IgG HT	**Positive**	123	0	0	123
	Negative	1	0	1	2
	Total	124	0	1	125

Positive Percent Agreement (PPA): 99.2% (123/124); 95% CI (95.6%-99.9%)
Negative Percent Agreement (NPA): 100% (1/1); 95% CI (20.7%-100%)

Clinical Performance- Known Negative Specimens (n=200)

		FDA Cleared VZV IgG comparator			
		Positive	**Equivocal**	**Negative**	**Total**
LIAISON VZV IgG HT	**Positive**	0	1	3	4
	Negative	0	6	190	196
	Total	0	7	193	200

Positive Percent Agreement (PPA): 0.0% (0/6); 95% CI (0.0%-39.0%)
Negative Percent Agreement (NPA): 97.9% (190/194); 95% CI (94.8%-99.2%)

Clinical performance- Normal Laboratory Routine Specimens (n=1083, ages 0-84)

		FDA Cleared VZV IgG comparator			
		Positive	**Equivocal**	**Negative**	**Total**
LIAISON VZV IgG HT	**Positive**	556	4	5	565
	Negative	10	5	503	518
	Total	566	9	508	1083

Positive Percent Agreement (PPA): 97.4% (556/571); 95% CI (95.7%-98.4%)
Negative Percent Agreement (NPA): 98.2% (503/512); 95% CI (96.7%-99.1%)

Clinical Performance- Pregnant Women (n=135)

		FDA Cleared VZV IgG comparator			
		Positive	**Equivocal**	**Negative**	**Total**
LIAISON VZV IgG HT	**Positive**	108	0	1	109
	Negative	0	2	24	26
	Total	108	2	25	135

Positive Percent Agreement (PPA): 98.2% (108/110); 95% CI (93.6%-99.5%)
Negative Percent Agreement (NPA): 96.0% (24/25); 95% CI (80.5%-99.3%)

Potential Interfering substances

The LIAISON VZV IgG HT assay was evaluated for potential interference caused by endogenous and exogenous substances using VZV IgG antibody negative, high negative, around the cut-off, low positive, and high positive samples. Controlled studies of potentially interfering substances showed no interference to each substance listed below in the LIAISON® VZV IgG HT, at the indicated concentration.

Substance	Concentrations tested
Endogenous Substances	
Unconjugated bilirubin	40 mg/dL
Conjugated bilirubin	40 mg/dL
Hemoglobin	1000 mg/dL
Triglycerides	3000 mg/dL
Human Serum Albumin	6000 mg/dL
Cholesterol	400 mg/dL
Total IgG	2000 mg/dL
Total IgM	400 mg/dL
Total protein (high)	≥ 120 g/L
Total protein (low)	≤ 60 g/L
Human anti-mouse antibody (HAMA)	820 ng/mL
Rheumatoid Factor (RF)	2000 IU/mL
Exogenous Substances	
Biotin	3500 ng/mL
Vitamin A	800 µg/dL
Vitamin B12	2850 pg/mL
Vitamin C	20 mg/dL
Vitamin D	450 ng/mL
Vitamin E	120 mg/L
Folic Acid	160 ng/mL
Acetaminophen	15.6 mg/dL
Ibuprofen	21.9 mg/dL
Acetylsalicylic acid	50 mg/dL
Naproxen	36.0 mg/dL
Penicillin	110 mg/dL
Streptomycin (sulphate)	25.8 mg/dL
Erythromycin	13.8 mg/dL

Potential Cross-Reactivity

The cross-reactivity study for the LIAISON® VZV IgG HT assay was designed to evaluate potential interference from antibodies to other viruses that may cause infectious diseases, as well as from other conditions. Samples for these studies were pre-screened with another commercially available VZV IgG assay. If found negative for VZV IgG antibodies, those specimens were used to study potential cross-reactivity. After the presence of potential cross-reactants in the samples was confirmed using US-marked assays, samples were tested with the LIAISON® VZV IgG HT assay. None of the specimens tested reactive with the LIAISON® XL VZV IgG HT assay. There is no evidence of cross reactivity with the tested medical conditions.

Condition	Number of tested samples	Assay Reactive results
CMV (anti-CMV positive)	10	0
Epstein-Bar Virus (anti-EBV positive)	10	0
Herpes Simplex Virus (anti-HSV 1 positive)	10	0
Herpes Simplex Virus (anti-HSV 2 positive)	10	0
Rubella (anti-Rubella positive)	10	0
Hepatitis C Virus (anti-HCV positive)	10	0
Human Immunodeficiency Virus (anti-HIV antibodies)	10	0
Hepatitis A Virus (anti-HAV positive)	10	0
Borrelia burgdorferi (anti-*B. burgorferi* antibodies)	10	0
Toxoplasma. gondii (anti-*T. gondii* antibodies)	11	0
Parvovirus B19 (anti-Parvovirus B19 positive)	16	0
Measles virus (anti-Measles antibodies)	11	0
Mumps virus (anti-Mumps antibodies)	12	0
Adenovirus (anti-Adenovirus antibodies)	10	0
Anti-Influenza A antibodies	11	0
Anti-Influenza B antibodies	12	0
Mycoplasma pneumonia (anti-*M. pneumonia* antibodies)	10	0
Respiratory syncytial virus (RSV) antibodies	11	0
Rheumatoid Factor (anti-Fc Immunoglobulin)	10	0
Human anti-mouse antibodies (HAMA)	14	0
Anti-nuclear antibodies (ANA)	10	0
Total	**226**	0

Precision

Within Laboratory Precision with LIAISON® XL Analyzer: A twenty-day precision study was performed in accordance with CLSI document EP5-A3, using a coded panel of seven (7) samples prepared by either spiking or diluting samples as necessary to obtain negative, near to cut off, low positive and positive samples. Kit Controls set was also included in the study. The panel samples and kit controls were tested with the LIAISON® VZV IgG HT assay in two (2) replicates per run, two (2) runs per day for twenty (20) operating days on one LIAISON® XL Analyzer, on three (3) assay lots.

Sample ID	N	Mean (S/CO)	Repeatability		Between Run		Between Day		Between-Lot		Total	
			SD	CV%	SD	CV %	SD	CV%	SD	CV%	SD	CV%
Negative Control A	240	0.0166	0.0012	7.3%	0.0017	10.4%	0.0021	13.0%	0.0021	12.8%	0.0034	20.7%
Negative Control B	240	0.0150	0.0018	11.9%	0.0014	9.6%	0.0020	13.2%	0.0023	15.3%	0.0035	23.5%
Positive Control A	240	3.73	0.069	1.8%	0.076	2.0%	0.211	5.7%	0.206	5.5%	0.285	7.6%
Positive Control B	240	3.57	0.079	2.2%	0.089	2.5%	0.216	6.1%	0.193	5.4%	0.289	8.1%
Positive Control C	240	3.49	0.070	2.0%	0.078	2.2%	0.199	5.7%	0.210	6.0%	0.279	8.0%
Sample 1	240	0.120	0.005	3.8%	0.003	2.8%	0.005	4.2%	0.009	7.1%	0.010	8.5%
Sample 2	240	0.669	0.021	3.1%	0.023	3.4%	0.029	4.4%	0.027	4.0%	0.047	7.0%
Sample 3	240	0.850	0.019	2.3%	0.021	2.4%	0.036	4.3%	0.065	7.7%	0.070	8.2%
Sample 4	240	1.26	0.030	2.4%	0.021	1.7%	0.055	4.4%	0.037	2.9%	0.072	5.7%
Sample 5	240	3.33	0.071	2.1%	0.053	1.6%	0.151	4.5%	0.099	3.0%	0.190	5.7%
Sample 6	240	6.84	0.13	1.8%	0.17	2.5%	0.26	3.9%	0.20	3.0%	0.37	5.4%
Sample 7	240	12.6	0.25	2.0%	0.44	3.5%	0.22	1.8%	0.40	3.1%	0.64	5.0%

Reproducibility: A five-day precision study was performed. The coded panel used in the 5-day study was the same panel used in the 20-day study. The coded panel was tested at all three (3) sites, using six (6) replicates per run in one (1) run per day for five (5) operating days. The CLSI Document EP-05A3 was consulted in the preparation of the testing protocol. The means, standard deviation, and coefficient of variation (%CV) of the results were computed for each of the tested specimens across sites.

Sample ID	N	Mean (S/CO)	Repeatability		Between Day		Between Site		Reproducibility	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
Negative Control	90	0.017	0.002	9.1%	0.001	7.6%	0.001	7.3%	0.002	13.0%
Positive Control	90	3.55	0.115	3.2%	0.135	3.8%	0.121	3.4%	0.201	5.7%
Sample 1	90	0.108	0.007	6.7%	0.010	9.4%	0.000	0.4%	0.011	10.4%
Sample 2	90	0.638	0.029	4.6%	0.042	6.6%	0.019	3.0%	0.050	7.8%
Sample 3	90	0.783	0.041	5.2%	0.054	6.9%	0.019	2.4%	0.064	8.1%
Sample 4	90	1.18	0.047	4.0%	0.079	6.7%	0.063	5.4%	0.104	8.8%
Sample 5	90	3.31	0.143	4.3%	0.176	5.3%	0.172	5.2%	0.267	8.1%
Sample 6	90	6.95	0.279	4.0%	0.187	2.7%	0.240	3.5%	0.388	5.6%
Sample 7	90	13.2	0.446	3.4%	0.427	3.2%	0.509	3.9%	0.756	5.7%

High-dose saturation effect

Whenever samples containing extremely high antibody concentrations are tested, the saturation effect can mimic concentrations lower than the real ones. However, a well-optimized two-step method excludes grossly underestimated results because the analytical signals remain consistently high (saturation curve).

Analysis of the saturation effect was evaluated by diluting three high-titer samples positive for VZV IgG. All samples resulted in concentration values above the assay range that would be expected with high-titer sera, indicating no sample misclassification and with no high-dose saturation effect observed.

Analytical sensitivity

In order to determine sensitivity of LIAISON® VZV IgG HT assay, the IgG to varicella-zoster virus concentration which corresponds to the measured signal of the cutoff value (1.0 S/CO) was read off the curves of serial dilutions of WHO *1st International Standard for varicella zoster immunoglobulin*, 1987 code W1044, in human negative serum. The data was analyzed by regression analysis, considering the best fit. Three lots of the LIAISON VZV IgG HT assay were used. The analytical sensitivity at the cutoff is the higher

concentration among the 3 lots. The analytical sensitivity of LIAISON® VZV IgG HT assay at cutoff level is 152.4 mIU/mL.

CONCLUSION:
As summarized, the DiaSorin LIAISON® VZV IgG HT and LIAISON® Control VZV IgG HT, 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 is as safe and effective as the predicate and does not raise new questions of safety and efficacy.