

K061820

5.0 510(k) SUMMARY

FEB 26 2007

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name: DiaSorin LIAISON® VZV IgG

Common Names/Descriptions:

Immunoassay for the detection of specific IgG antibodies to varicella-zoster virus (VZV IgG).

Classification Names:

Varicella-zoster virus Serological Reagents

Product Code:

LFY

PREDICATE DEVICE:

Diamedix Is-VZV IgG Test System, K981867

DEVICE DESCRIPTION:

INTENDED USE: The DiaSorin LIAISON® VZV IgG uses chemiluminescence immunoassay (CLIA) technology on the LIAISON® Analyzer 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.

KIT DESCRIPTION: The method for the qualitative determination of specific IgG to varicella-zoster virus is an indirect chemiluminescence immunoassay (CLIA). All assay steps and incubations are performed by the LIAISON® Analyzer.

Varicella-zoster virus antigen is used for coating magnetic particles (solid phase) and a mouse monoclonal antibody to human IgG is linked to an isoluminol derivative (isoluminol-antibody conjugate). During the first incubation, anti-VZV IgG antibodies, present in calibrators, samples or controls, bind to the solid phase. After each incubation, the unbound material is removed with a wash cycle. During the second incubation, the antibody conjugate reacts with anti-VZV IgG already bound to the solid phase. Subsequently, the starter reagents are added and a flash chemiluminescence reaction is induced. The light signal, directly related to the amount of isoluminol-antibody conjugate, is measured by a photomultiplier as relative light units (RLU) and is indicative of the presence of anti-VZV IgG in calibrators, samples or controls.

PERFORMANCE DATA:

COMPARATIVE CLINICAL TRIALS: The clinical trials were conducted at two external U.S. laboratories and at DiaSorin. Testing was performed on prospectively-collected U.S. samples as defined below. The samples were tested by LIAISON® VZV IgG and a comparison assay, at the trial sites per the manufacturers' instructions for use.

Specimens that were equivocal by both assays were not included in the percent agreement calculation. Positive or negative results from the LIAISON® VZV IgG assay were considered as non-agreements in the calculation of percent positive agreement and percent negative agreement when the corresponding reference assay result was equivocal.

Compares number of samples positive on both assays to sum of all positive samples on the reference assay + samples equivocal on the reference assay and negative on the LIAISON® VZV IgG.
 Compared number of samples negative on both assay to sum of all negative samples on the reference assay + samples equivocal on the reference assay and positive on the LIAISON® VZV IgG

Prospective samples: Subjects Sent to the Laboratory for varicella-zoster virus testing:

DiaSorin LIAISON® VZV IgG	VZV IgG ELISA			Total
	Positive	Equivocal	Negative	
Positive	659	7	4	670
Equivocal	1	1	1	3
Negative	3	4	65	72
Total	663	12	70	745

	Percent Agreement	Exact 95% confidence interval
Positive	98.8% (659/667)	97.7 – 99.5%
Negative	84.4% (65/77)	74.4 – 91.7%

Prospective Samples: Pregnant Women

LIAISON® VZV IgG Results	VZV IgG ELISA Results			
	Positive	Equivocal	Negative	Total
Positive	645	11	3	659
Equivocal	3	0	0	3
Negative	2	0	25	27
Total	650	11	28	689

	Percent Agreement	Exact 95% confidence interval
Positive	99.2% (645/650)	98.2 – 99.7%
Negative	64.1% (25/39)	47.6 – 78.8%

REPRODUCIBILITY: Reproducibility studies were performed at 3 sites in a five-day protocol outlined in CLSI document, EP15-A2. The study included 3 different LIAISON® VZV IgG kit lots. Each site used a different lot of the LIAISON® VZV IgG Assay for the study. A coded panel comprised of 9 frozen repository samples, prepared representing negative levels, low positive to mid-positive analyte levels, and moderate to high positive levels, was used in this study. The study also included the LIAISON® VZV IgG controls (Neg Ctl and Pos Ctl) which are marketed in Europe, an internal serum borderline control (011006) and a commercially marketed serum ToRCH Negative and Positive Control (BR Neg Ctl and BR Pos Ctl). Results expressed as an Index value are summarized in the following table.

		Mean	Within-run	Within-run	Between-run	Between-run	Between-site	Between-site	Overall	Overall
ID#	N	Index	sd	%CV	sd	%CV	sd	%CV	sd.	%CV
DiaSorin Neg Ctl	60	30.3	2.97	9.0	4.52	7.87	3.88	12.8	5.64	18.6
DiaSorin Pos Ctl	60	434	42.6	9.81	48.9	9.21	40.3	9.29	62.4	14.4
011006 (Cutoff Ctl)	60	246	22.8	9.44	26.4	10.2	13.6	5.54	33.9	13.8
<i>BR Neg Ctl (100% serum)</i>	<i>60</i>	<i><10</i>	<i>15.0</i>	<i>5.53</i>	<i>18.0</i>	<i>6.15</i>	<i>4.0</i>	<i>1.62</i>	<i>23.0</i>	<i>8.24</i>
BR Pos Ctl (100% serum)	60	863	86.4	10.2	70.6	8.05	27.8	3.22	108	12.6
3314	60	60.2	3.81	6.54	3.74	5.42	1.04	4.01	5.75	9.54
3360	60	265	19.5	7.35	29.3	7.59	6.88	9.75	34.2	12.9
3385	60	242	22.0	8.98	26.1	7.63	4.67	9.63	33.5	13.8
3403	60	164	8.23	4.86	13.1	5.73	0.73	6.96	14.9	9.14
3492	60	276	24.8	9.08	24.4	7.62	7.89	6.08	33.9	12.3
3515	60	252	27.4	10.6	24.9	8.42	7.12	6.25	36.5	14.5
3554	60	291	26.0	8.68	28.6	7.94	14.0	5.83	41.5	14.3
Pos 5	60	1530	227	14.6	184	10.2	138	7.02	291	19.0
Pos 9	60	679	60.6	9.06	57.1	7.79	38.8	1.20	82.7	12.2

BR Neg Ctl Index was below the reading range of the assay therefore; the precision calculations are based on signal (RLU) for this sample.

The assay precision performance was established at DiaSorin following a protocol outlined in CLSI document, EP5-A2. The same serum samples and controls described in the five-day study were tested in quadruplicate over 20 working days on one LIAISON® instrument and one kit lot.

Results

The results, expressed as an Index value, are summarized in the following table as sample global mean Index; mean %CV's computed for within run, between run, and total.

ID#	N	mean (Index)	within run sd	within run %CV	between run sd	between run %CV	overall sd	overall %CV
DiaSorin Neg Ctl	40	36.3	3.0	8.53	6.86	18.90	7.20	20.05
DiaSorin Pos Ctl	40	446	19.4	4.41	86.70	19.48	88.62	20.07
011006 (Cutoff Ctl)	40	271	18.3	6.78	43.45	16.06	45.62	17.01
<i>BR Neg Ctl (100% serum Ctl)</i>	40	<10	10.8	4.14	31.12	12.07	32.39	12.62
BR Pos Ctl (100% serum Ctl)	40	952	64.0	7.07	174.41	18.32	182.54	19.25
3314	40	60.8	2.9	4.94	7.46	12.28	7.86	13.00
3360	40	318	17.6	5.45	52.09	16.39	53.23	16.85
3385	40	292	6.9	2.40	66.92	22.94	66.39	23.02
3403	40	164	8.5	5.04	23.78	14.53	24.18	14.80
3492	40	330	22.0	6.83	50.39	15.27	54.36	16.62
3515	40	280	10.2	3.62	40.86	14.60	41.14	14.79
3554	40	286	21.1	7.10	48.00	16.77	51.07	18.00
Pos 5	40	1761	97.2	5.56	337.11	19.37	344.93	19.79
Pos 9	40	769	26.2	3.38	127.97	16.64	126.33	16.50

BR Neg Ctl Index was below the reading range of the assay therefore; the precision calculations are based on signal (RLU) for this sample.

CONCLUSION

The submitted material in this premarket notification is complete and supports a substantial equivalence decision. The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.



Food and Drug Administration
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FEB 26 2007

Re: k061820
Trade/Device Name: LIAISON® VZV IgG
Regulation Number: 21 CFR 866.3900
Regulation Name: Varicella-Zoster virus Serological Reagents
Regulatory Class: Class II
Product Code: LFY
Dated: February 13, 2007
Received: February 16, 2007

Dear Ms. Meyer:

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.

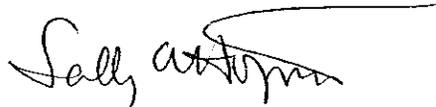
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATIONS FOR USE

510(k) Number (if known): K061820

Device Name: LIAISON® VZV IgG

Indications For Use: The LIAISON® VZV IgG Assay uses chemiluminescence immunoassay (CLIA) technology on the LIAISON® Analyzer for the qualitative detection of specific IgG antibodies to varicella-zoster virus in human serum. This assay can be used as an aid in the determination of previous infection of varicella-zoster virus.

Prescription Use X
(Part 21 CFR 801 Subpart D)

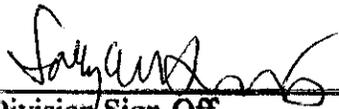
AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 4



Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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