510(k) Summary of Safety and Effectiveness

Plexus™ HerpeSelect® HSV 1 and 2 IgG (with software)
Catalog Number: MP0900G
Prepared: September 24, 2007

Applicant	Focus Diagnostics, Inc. 10703 Progress Way Cypress, California 90630 USA
Establishment Registration No.	2023365
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Summary Date	September 24, 2007
Proprietary Name	Plexus™ HerpeSelect® HSV 1 and 2 IgG (with software)
Generic Name	Herpes Simplex Virus Types 1 and 2 Serological Assays
Classification	Class II
Predicate Device	HerpeSelect 1 and 2 Immunoblot IgG

OCT 5 2007

Device Description

The Focus Diagnostics Plexus™ HerpeSelect® HSV 1 and 2 IgG (with software) is a multiplexed immunoassay for qualitatively detecting and differentiating human IgG antibodies to HSV-1 and HSV-2. Test principle is identical to the predicate device.

Intended Use

The Focus Diagnostics Plexus™ HerpeSelect® HSV 1 and 2 IgG (with software) is intended for qualitatively detecting the presence or absence of human IgG antibodies to HSV-1 and HSV-2 in human sera. The test is indicated for pregnant women and sexually active adults, as an aid for presumptively diagnosing HSV-1 and HSV-2 infection. The predictive value of a positive or negative result depends on the population's prevalence and the pretest likelihood of HSV-1 and HSV-2 infection. The test is not intended for donor screening or for self-testing. The performance of this assay has not been established for use in a pediatric population, for neonatal screening, for testing of immunocompromised patients, for use by a point of care facility or for use with automated equipment.

Test Principle

The Focus Diagnostics HerpeSelect®1 and 2 Plexus IgG uses an Antigen Bead suspension that contains two distinct HSV antigen bead types that fluoresce at different wavelengths and/or intensities: gG-1 beads and gG-2 beads. The Focus Diagnostics HerpeSelect®1 and 2 Multiplex IgG is a three step procedure.

1. Patient sera are diluted, and the diluted sera are incubated with Antigen Beads. If HSV antibodies are present, then the antibodies bind to the corresponding antigen beads.
2. Phycoerythrin—conjugated goat anti-human IgG, (Conjugate) is added, and the Conjugate binds to the bound HSV antibody (if present), and forms a Conjugate-HSV antibody-antigen bead sandwich.
3. Fluorescence from each distinct HSV antigen bead type is measured and compared against a Cut-off Calibrator.

Performance Characteristics

Studies to Validate Plexus™ HerpeSelect® HSV 1 and 2 IgG (with software)

Testing was done at two external sites and one internal site to confirm that assay results obtained using Plexus Software are identical to results calculated manually using the instrument (Luminex) raw data.

Agreement between Index Calculated with Plexus Software and Index Calculated Manually (n = 600)		
Sample Type	**n**	**% Agreement; 95% Confidence Interval**
HSV-1 Pos	161/161	100%; 95% CI: 0.977 – 1.00
HSV-1 Eqv	4/4	100%; 95% CI: 0.398 – 1.00
HSV-1 Neg	134/134	100%; 95% CI: 0.973 – 1.00
HSV-1 Invalid	1/1	-
HSV-2 Pos	139/139	100%; 95% CI: 0.974 – 1.00
HSV-2 Eqv	7/7	100% ; 95% CI: 0.590 – 1.00
HSV-2 Neg	153/153	100%; 95% CI: 0.976 – 1.00
HSV-1 Invalid	1/1	-

100% of HSV-1 indexes and 100% of HSV-2 indexes calculated using the Plexus software matched the indexes calculated manually.

Summary of Previous Studies for Plexus™ HerpeSelect® HSV 1 and 2 IgG (manual calculation)

Study		Plexus HerpeSelect 1 Results	Plexus HerpeSelect 2 Results
Pregnant Women (Indicated population)	Specificity Sensitivity	96.5% 92.2%	94.3% 95.5%
Sexually Active Adults (Indicated population)	Specificity Sensitivity	91.0% 96.5%	96.3% 97.4%
CDC HSV/CMV Panel	Agreement with positives Agreement with negatives	100% 100%	100% 100%
Low Prevalence Population	Agreement with negatives	97.9%	100%
Cross-reactivity with CMV, EBV and VZV.	Cross-reactivity	0-5%	0-3%
Reproducibility	%CV of positives	≤10%	≤10%

Sensitivity and Specificity with Pregnant Women (n = 300)

Focus (n = 150) and an external investigator (n = 150) assessed the device's reactivity with sera from pregnant women. The sera were sequentially submitted to the laboratory, archived, and masked. The external investigator was a University laboratory located in Northern California, and the sera were collected in the Pacific Northwestern United States. The gold-standard reference method was the Focus Diagnostics HerpeSelect 1 and 2 Immunoblot IgG for calculation of sensitivity and specificity. The device was also evaluated with the HerpeSelect2 ELISA IgG a cleared predicate device which is not required for regulatory clearance for typing assay.

HSV-1 Sensitivity and Specificity

The Focus HerpeSelect 1 Immunoblot IgG was:
HSV-1 positive for 170 samples,
HSV-1 negative with 128 samples, and
HSV Common Antigen band positive for two samples.

The Plexus HerpeSelect 1 agreed with:
96.5% (164/170) of Immunoblot positives, and
92.2% (118/128) of Immunoblot negatives.
The two Immunoblot HSV Common Antigen band positives were both negative in the Plexus.

HSV-2 Sensitivity and Specificity

The Focus HerpeSelect 2 Immunoblot IgG was:
HSV-2 positive for 122 samples,
HSV-2 negative with 176 samples, and
HSV Common Antigen band positive for two samples.

The Plexus HerpeSelect 2 agreed with:
94.3% (115/122) of Immunoblot positives, and
95.5% (168/176) of Immunoblot negatives.
The two Immunoblot HSV Common Antigen band positives were both negative in the Plexus.

Plexus HerpeSelect 1 IgG Reactivity with Expectant Mothers (n = 300)

Lab	Herpe-Select Immunoblot	Plexus HerpeSelect-1					HerpeSelect-1 ELISA				
		n	Neg	Eqv	Pos	Sensitivity and Specificity	n	Neg	Eqv	Pos	% Agreement
Focus and Site 1	Pos	170	6	0	164	96.5% (164/170) 95%CI 92.5-98.7%	170	5	1	164	96.5% (164/170) 95%CI 92.5-98.7%
Focus and Site 1	Neg	128	118	3	7	92.2% (118/128) 95%CI 86.1-96.2%	128	118	3	7	92.2% (118/128) 95%CI 86.1-96.2%
Focus and Site 1	Com	2	2	0	0	Na	2	2	0	0	Na

Plexus HerpeSelect 2 IgG Reactivity with Expectant Mothers (n = 300)

Lab	Herpe-Select Immunoblot	Plexus HerpeSelect-2					HerpeSelect-2 ELISA				
		n	Neg	Eqv	Pos	Sensitivity and Specificity	n	Neg	Eqv	Pos	% Agreement
Focus and Site 1	Pos	122	5	2	115	94.3% (115/122) 95%CI 88.5-97.7%	122	3	0	119	97.5% (119/122) 95%CI 93.0-99.5%
Focus and Site 1	Neg	176	168	3	5	95.5% (168/176) 95%CI 91.2-98.0%	176	166	1	9	94.3% (166/176) 95%CI 89.8-97.2%
Focus and Site 1	Com	2	2	0	0	Na	2	2	0	0	Na

Reactivity with Sexually Active Adults (n = 300)

Focus (n = 150) and an external investigator (n = 150) assessed the device's reactivity with sera from sexually active adults. The sera were sequentially submitted to the laboratory, archived, and masked. The external investigator was a clinical laboratory located in Southern California, and the sera were collected in the Pacific Northwestern United States. The gold-standard reference method was the Focus Diagnostics HerpeSelect 1 and 2 Immunoblot IgG for calculation of sensitivity and specificity. The device was also evaluated with the HerpeSelect2 ELISA IgG a cleared predicate device which is not required for regulatory clearance for typing assay.

HSV-1 Sensitivity and Specificity

The Focus HerpeSelect 1 Immunoblot IgG was:
HSV-1 positive for 157 samples,
HSV-1 negative with 142 samples, and
HSV Common Antigen band positive for one sample.

The Plexus HerpeSelect 1 agreed with:
91.0% (142/156) of Immunoblot positives (one sample was not run on the Plexus device), and
96.5% (137/142) of Immunoblot negatives.

HSV-2 Sensitivity and Specificity

The Focus HerpeSelect 2 Immunoblot IgG was:
HSV-2 positive for 109 samples,
HSV-2 negative with 190 samples, and
HSV Common Antigen band positive for one sample.

The Plexus HerpeSelect 2 agreed with:
96.3% (105/109) of Immunoblot positives, and
97.4% (184/189) of Immunoblot negatives (one sample was not run on the Plexus device).

Plexus HerpeSelect 1 IgG Reactivity with Sexually Active Adults (n = 300)

Lab	Herpe-Select Immun oblot	Plexus HerpeSelect-1					HerpeSelect-1 ELISA				
		n	Neg	Eqv	Pos	Sensitivity and Specificity	n	Neg	Eqv	Pos	% Agreement
Focus and Site 2	Pos	156	9	5	142	91.0% (142/156) 95%CI 85.4-95.0%	157	7	2	147	93.6% (147/157) 95%CI 88.6-96.9%
Focus and Site 2	Neg	142	137	3	2	96.5% (137/142) 95%CI 92.0-98.9%	142	137	1	4	96.5% (137/142) 95%CI 92.0-98.9%
Focus and Site 2	Com	1	1	0	0	na	1	1	0	0	na

*One of 300 samples was not run in the Plexus HerpeSelect, and that one sample was HSV-1 negative/HSV-2 positive in the Immunoblot.

Plexus HerpeSelect 2 IgG Reactivity with Sexually Active Adults (n = 300)

Lab	Herpe-Select Immun oblot	Plexus HerpeSelect-2					HerpeSelect-2 ELISA				
		n	Neg	Eqv	Pos	% Agreement	n	Neg	Eqv	Pos	% Agreement
Focus and Site 2	Pos	109	3	1	105	96.3% (105/109) 95%CI 90.9-99.0%	109	1	1	107	98.2% (107/109) 95%CI 93.5-99.8%
Focus and Site 2	Neg	189	184	1	4	97.4% (184/189) 95%CI 93.9-99.1%	190	186	1	3	97.9% (186/190) 95%CI 94.7-99.4%
Focus and Site 2	Com	1	1	0	0	na	1	1	0	0	na

*One of 300 samples was not run in the Plexus HerpeSelect, and that one sample was HSV-1 negative/HSV-2 positive in the Immunoblot.

Agreement with CDC Panel (n = 100)

The following information is from a serum panel obtained from the CDC and tested by Focus Diagnostics. The results are presented as a means to convey further information on the performance of this assay with a masked, characterized serum panel. This does not imply an endorsement of the assay by the CDC.

The test panel consists of 100 samples. This panel contains duplicate samples of 50 test sera. The duplicates serve to test for reproducibility. There are 16 HSV-1 positive, 7 HSV-2 positive, 11 double-positive and 16 double-negative sera resulting in 54 HSV-1 positive and 36 HSV-2 positive specimens.

Determination of positive and negative samples

Of the 54 HSV-1 positive samples, the HerpeSelect® Plexus IgG correctly identified 100% (54/54).
Of the 36 HSV-2 positive samples, the HerpeSelect® Plexus IgG correctly identified 100% (36/36).
Of the 22 double positive samples, the HerpeSelect® Plexus IgG correctly identified 100% (22/22).
Of the 32 double negative samples, the HerpeSelect® Plexus IgG correctly identified 100% (32/32).

Agreement with CDC Panel (n = 100)

Sample Type	CDC Result		n	HerpeSelect-1 Plexus Results				HerpeSelect-2 Plexus Results			
	HSV1	HSV2		Neg	Eqv	Pos	% Agreement	Neg	Eqv	Pos	% Agreement
HSV-1 Positive	Pos	Neg	32	0	0	32	100% (32/32) 95%CI 89.1-100%	32	0	0	100% (32/32) 95%CI 89.1-100%
HSV-2 Positive	Neg	Pos	14	14	0	0	100% (14/14) 95%CI 76.8-100%	0	0	14	100% (14/14) 95%CI 76.8-100%
Dual Positive	Pos	Pos	22	0	0	22	100% (22/22) 95%CI 84.6-100%	0	0	22	100% (22/22) 95%CI 84.6-100%
Dual **Negative**	Neg	Neg	32	32	0	0	100% (32/32) 95%CI 89.1-100%	32	0	0	100% (32/32) 95%CI 89.1-100%

CDC Panel Reproducibility

All paired sera were correctly identified: The Focus Diagnostics HerpeSelect® 1 and 2 Plexus IgG identified 16 out of 16 paired HSV-1 positive and HSV-2 negative (100%), 7 out of 7 paired HSV-2 positive and HSV-1 negative (100%), 11 out of 11 paired double-positive (100%) and 16 out of 16 paired double-negative (100%) samples.

Specificity with a Low Prevalence Population (n = 77)

Focus (n = 77) assessed the device's reactivity with sera from a low prevalence population. Focus selected sera from patients aged 18 and 19 years, and that had been submitted to a clinical laboratory in Southern California from states having a history of low sexually transmitted disease prevalence. Focus excluded sera that were submitted for sexually transmitted diseases, herpesvirus testing, and tests indicating the patient may be immunocompromised. The sera were sequentially selected, archived and masked. The HerpeSelect Plexus results were compared to the Focus HerpeSelect 1 and 2 Immunoblot IgG.

HSV-1 Reactivity

The Focus HerpeSelect 1 Immunoblot IgG was: HSV-1 positive for 28 samples, HSV-1 negative with 47 samples, and HSV Common Antigen band positive for two samples.

The Plexus HerpeSelect 1 agreed with: 96.4% (27/28) of Immunoblot positives (one HSV-1 Immunoblot positive was equivocal in the Plexus device), and 97.9% (46/47) of Immunoblot negatives (one HSV-1 Immunoblot negative was positive in the Plexus device).

One Immunoblot HSV Common Antigen band positive was equivocal in the Plexus, and the other sample was Plexus negative.

HSV-2 Reactivity

The Focus HerpeSelect 2 Immunoblot IgG was: HSV-2 positive for four samples, HSV-2 negative with 71 samples, and HSV Common Antigen band positive for two samples.

The Plexus HerpeSelect 2 agreed with: 75.0% (3/4) of Immunoblot positives (one HSV-1 Immunoblot positive was equivocal in the Plexus device), and 100% (71/71) of Immunoblot negatives (one HSV-1 Immunoblot negative was positive in the Plexus device). Both Immunoblot HSV Common Antigen band positives were negative in the Plexus.

Specificity with Low Prevalence Population (n = 77)

HerpeSelect Immunoblot	Plexus HerpeSelect-1					Plexus HerpeSelect-2				
	n	Neg	Eqv	Pos	Sensitivity and Specificity	n	Neg	Eqv	Pos	Sensitivity and Specificity
Positive	28	0	1	27	96.4% (27/28) 95%CI 81.6-99.9%	4	0	1	3	75.0% (3/4) 95%CI 19.4-99.4%
Negative	47	46	0	1	97.9% (46/47) 95%CI 88.7-99.9%	71	71	0	0	100% (71/71) 95%CI 94.9-100%
Common	2	1	1	0	NA	2	2	0	0	NA

Cross-reactivity (n = 51)

Focus assessed cross-reactivity with two groups of samples: a "HSV ELISA dual negative" group (n=37), and a "HSV ELISA mixed sero-reactivity" group (n=14).

The HSV ELISA dual negative group (n=37) included samples that were sero-negative with both the HerpeSelect-1 ELISA IgG and HerpeSelect 2 ELISA IgG, and were sero-positive by at least one of
a FDA cleared CMV ELISA IgG (n = 18),
a home brerw VZV ACIF (n=32),
a FDA cleared EBV VCA IgG (n=31).
The HerpeSelect 1 and 2 Plexus IgG was HSV-1 negative with all but one of the HSV ELISA dual negatives, and equivocal with one sample (the one sample was CMV+ VZV+ and EBV+).
The HerpeSelect 1 and 2 Plexus IgG was HSV-2 negative with all but one of the HSV ELISA dual negatives, and equivocal with one sample (the one sample was CMV- VZV+ and EBV+).

The HSV ELISA mixed reactivity group (n=14) included samples that were sero-positive with either the HerpeSelect-1 ELISA IgG or HerpeSelect 2 ELISA IgG, and were sero-positive by at least one of
a FDA cleared CMV ELISA IgG (HSV-1 neg n = 2, HSV-2 neg n = 9),
a home brew VZV ACIF (HSV-1 neg n = 1, HSV-2 neg n = 2),
a FDA cleared EBV VCA IgG (HSV-1 neg n = 1, HSV-2 neg n = 0).
The HerpeSelect 1 and 2 Plexus IgG was HSV-1 negative with all of the HSV-1 ELISA negatives in the mixed reactivity group.
The HerpeSelect 1 and 2 Plexus IgG was HSV-2 negative with all of the HSV-2 ELISA negatives in the mixed reactivity group.

Cross-reactivity (n = 51)

Cross-reactant	HSV ELISAs	HerpeSelect-1 Plexus					HerpeSelect-2 Plexus				
		n	Neg	Eqv*	Pos	%Pos	n	Neg	Eqv†	Pos	%Pos
CMV IgG +	Dual Neg	18	17	1	0	5.6% (1/18) 95%CI 0.1-27.3%	18	18	0	0	0.0% (0/18) 95%CI 0.0-18.5%
	+/- or -/+	2	2	0	0	0.0% (0/2) 95%CI 0.0-84.2%	9	9	0	0	0.0% (0/9) 95%CI 0.0-33.6%
	Total	20	19	1	0	5.0% (1/20) 95%CI 0.1-24.9%	27	27	0	0	0.0% (0/27) 95%CI 0.0-12.8%
VZV IgG +	Dual Neg	32	31	1	0	3.1% (1/32) 95%CI 0.1-16.2%	32	31	1	0	3.1% (1/32) 95%CI 0.1-16.2%
	+/- or -/+	1	1	0	0	0.0% (0/1) NA	2	2	0	0	0.0% (0/2) 95%CI 0.0-84.2%
	Total	33	32	1	0	3.0% (1/33) 95%CI 0.1-15.8%	34	33	1	0	2.9% (1/34) 95%CI 0.1-15.3%
EBV IgG +	Dual Neg	31	30	1	0	3.2% (1/31) 95%CI 0.1-16.7%	31	30	1	0	3.2% (1/31) 95%CI 0.1-16.7%
	+/- or -/+	1	1	0	0	0.0% (0/1) NA	0	0	0	0	NA
	Total	32	31	1	0	3.1% (1/32) 95%CI 0.1-16.2%	31	30	1	0	3.2% (1/31) 95%CI 0.1-16.7%

* The HerpeSelect-1 Plexus was equivocal with one sample, and the sample was IgG positive for CMV, VZV and EBV.
† The HerpeSelect -2 Plexus was equivocal with one sample, and the sample was IgG positive for VZV and EBV.

Inter-laboratory Reproducibility and Inter/Intra-assay Reproducibility

Focus, a clinical laboratory located in Southern California, and a university laboratory located in Northern California assessed the device's inter-laboratory reproducibility and inter/intra-assay reproducibility. Each of the three laboratories tested eleven samples in triplicate on five different days.

Inter-laboratory Reproducibility and Inter/Intra-assay Reproducibility[a]

	HerpeSelect 1 Plexus IgG Results					HerpeSelect 2 Plexus IgG Results				
	Intra- and Inter-assay			Inter-Lab		Intra- and Inter-assay			Inter-Lab	
Sample	Mean Index	Intra-assay % CV	Inter-assay % CV	Mean Index	% CV	Mean Index	Intra-assay % CV	Inter-assay % CV	Mean Index	% CV
9	4.93	3.6	10.3	4.94	3.7	3.88	3.4	10.0	3.87	2.5
6	4.24	3.8	8.7	4.22	3.3	4.90	2.6	8.5	4.89	2.1
2	3.87	4.8	7.9	3.86	1.3	3.36	4.3	7.7	3.35	2.0
8	3.27	4.9	9.1	3.25	3.0	4.56	3.1	8.3	4.55	1.5
4	3.24	4.9	7.4	3.22	2.1	2.55	4.5	8.9	2.54	5.8
1	3.04	4.3	8.9	3.02	2.3	2.71	3.8	9.3	2.70	2.1
12[b]	2.13	7.9	8.7	2.13	4.1	1.87	7.2	8.8	1.87	3.4
3	0.34	9.1	14.9	0.34	6.8	0.06	8.7	28.3	0.06	22.6
10[c]	0.19	9.9	213.1	0.19	59.0	0.12	11.4	334.2	0.40	103.8
10[d]	0.13	10.0	15.8	0.12	1.9	0.06	11.5	41.7	0.06	38.3
7	0.18	8.3	16.3	0.17	9.4	0.06	8.1	23.7	0.06	17.3
5	0.14	9.0	16.0	0.14	2.7	0.06	8.3	39.8	0.06	38.1

a. Excludes two runs at one site that were invalid because the Negative Control index was beyond the acceptable QC criteria (it appears that the Positive Control was run in those wells since the indices were about 1.9 for both gG1 and gG2)
b. Samples 12 (inter-lab reproducibility) and 14 (inter-lot reproducibility below) were separate samples, but they were made with the same sera Samples 11 did not have sufficient volume to be sent to investigators.
c. This line includes all data for Sample 10, including one run at Lab 2, where it appears that Sample 1 may have been run instead since the indices were about 2.7 for both gG1 and gG2.
d. This line includes all data for Sample 10, except for one run at Lab 2, where it appears that Sample 1 may have been run instead since the indices were about 2.7 for both gG1 and gG2.

Inter-Lot Reproducibility

Focus assessed the device's Inter-lot Reproducibility by testing eleven samples with three separate lots. The samples were run in triplicate. Each lot had a different set of gG-1 and gG2 beads, a different lot of conjugate (made from 2 different stock conjugates), and a different lot of calibrator (made from 2 different combinations of positive and negative sera). The results of the studies are summarized in the tables below:

Inter-lot Reproducibility

Sample	HSV-1		HSV-2	
	Mean Index	Inter-Lot %CV	Mean Index	Inter-Lot %CV
9	5.20	7.4	3.90	12.8
6	4.36	8.5	4.76	9.2
2	3.60	7.3	3.19	9.3
4	3.29	7.9	2.54	6.4
8	3.23	11.3	4.45	9.4
1	3.14	5.8	2.73	4.8
12/14*	2.22	10.5	1.86	7.8
3	0.31	17.0	0.11	50.9
7	0.15	31.3	0.08	21.8
5	0.10	45.6	0.06	24.9
10	0.09	50.6	0.06	26.9

* Samples 12 (inter-lab reproducibility above) and 14 (inter-lot reproducibility) were separate samples, but they were made with the same sera. Samples 11 and 13 did not have sufficient volume to be sent to investigators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Constance Bridges, MBA, RAC, ASQ-CBA
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Focus Diagnostics, Inc.
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OCT 5 ˇ 2007

Re: k071511
Trade/Device Name: Plexus™ HerpeSelect® HSV 1 and 2 IgG (with software)
Regulation Number: 21CFR 866.3305
Regulation Name: Herpes simplex virus serological reagents
Regulatory Class: Class II
Product Code: MXJ, MYF
Dated: September 5, 2007
Received: September 10, 2007

Dear Ms. Bridges:

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 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); 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.

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276- 0100. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

510(k) Number (if known): **K071511**

Device Name: Plexus™ HerpeSelect® HSV 1 and 2 IgG (with software)

Indications for Use: The Focus Diagnostics Plexus™ HerpeSelect® HSV 1 and 2 IgG (with software) is intended for qualitatively detecting the presence or absence of human IgG antibodies to HSV-1 and HSV-2 in human sera. The test is indicated for pregnant women and sexually active adults, as an aid for presumptively diagnosing HSV-1 and HSV-2 infection. The predictive value of a positive or negative result depends on the population's prevalence and the pretest likelihood of HSV-1 and HSV-2 infection. The test is not intended for donor screening or for self-testing. The performance of this assay has not been established for use in a pediatric population, for neonatal screening, for testing of immunocompromised patients, for use by a point of care facility or for use with automated equipment.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K071511