DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

Quest International, Inc.
Dr. David J. Kiefer, Ph.D.
Director, Research and Development
8127 NW 29th Street
Miami, FL 33122

May 13, 2016

Re: K152353
Trade/Device Name: SeraQuest HSV Type 2 Specific IgG
Regulation Number: 21 CFR 866.3305
Regulation Name: Herpes simplex virus serological assays
Regulatory Class: Class II
Product Code: MYF
Dated: April 14, 2016
Received: April 14, 2016

Dear Dr. Kiefer:

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 Parts 801 and 809); 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

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
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)*
K152353

Device Name
SeraQuest HSV Type 2 Specific IgG

Indications for Use *(Describe)*
1. Intended Use: For In Vitro Diagnostic Use Only. The SeraQuest HSV Type 2 Specific IgG assay is an enzyme-linked immunosorbent assay (ELISA) intended for the qualitative detection of human IgG antibodies to type 2 herpes simplex virus (HSV) in human serum. The test is indicated for sexually active individuals and expectant mothers as an aid in the presumptive diagnosis of HSV-2 infection. The predictive value of a positive or negative result depends on the prevalence of HSV-2 infection in the population and the pre-test likelihood of HSV-2 infection.

The test is not FDA cleared for screening blood or plasma donors. The performance of this assay has not been established for immunocompromised patients, pediatric patients or matrices other than human serum.

2. For In Vitro Diagnostic Use Only.

3. A positive result indicates previous exposure to Type 2 Herpes Simplex Virus.

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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Quest International, Inc., 8127 NW 29th Street, Miami, FL 33122

5. 510k Summary

510(k) Summary

Applicant: Quest International, Inc.
8127 NW 29th Street
Doral, FL. 33122

Registration No. 1061839

Contact Person: David J. Kiefer, Ph.D.

Telephone: 305 592-6991

Telefax: 305 592-6834

Device: SeraQuest® HSV Type 2 Specific IgG

Medical Device Group: In vitro diagnostic

Device Classification: Class 2

Catalogue Number: 01-420

Description:

The SeraQuest® HSV Type 2 Specific IgG test is a solid-phase enzyme-linked immunoassay (ELISA) , which is performed in microwells, at room temperature, and in three thirty minute incubations The test detects IgG antibodies which are directed against HSV 2 type-specific antigens in human serum. The Calibrator in the SeraQuest® HSV Type 2 Specific IgG test set has been assigned Index values based on an in-house standard. Test results are reported as Index values. The following table shows the interpretation of results:

Index	Result	Interpretation
$\leq$ 0.9	Negative	No HSV-2 IgG antibodies detected. Patient is presumed not to have had a previous HSV-2 infection.
0.9 < X < 1.0	Equivocal	Obtain an additional sample for re-testing
$\geq$ 1.0	Positive	IgG antibody to HSV-2 detected.

Notes:

1. A single positive result only indicates previous immunologic exposure; the level of antibody response may not be used to determine active infection or disease stage.

2. When equivocal results are obtained, another specimen should be obtained ten to fourteen days later, and tested in parallel with the initial specimen. If the second specimen is also

equivocal, the patient is negative for primary or recent infection, and equivocal for antibody status. If the second sample is positive, the patient can be considered to have previous experience with HSV-2 infection.

3. Values obtained with different manufacturer's assay methods may not be used interchangeably. The magnitude of the reported IgG index value cannot be correlated to an endpoint titer. The magnitude of results above the cut-off is not an indicator of total antibody present.

Principle:

Diluted patient samples are incubated in antigen-coated wells. HSV Type 2 antibodies, if present in the patient sample, are immobilized in the wells by binding to the antigen. Residual sample is eliminated by washing and draining, and conjugate (enzyme-labeled antibodies to human IgG) is added and incubated. If IgG antibodies to HSV-2 are present, the conjugate will be immobilized in the wells. Residual conjugate is eliminated by washing and draining, and the substrate is added and incubated. In the presence of the conjugate, the substrate is converted to a yellow end-product which is read photometrically.

Intended Use:

Intended Use: For In Vitro Diagnostic Use Only. The SeraQuest HSV Type 2 Specific IgG assay is an enzyme-linked immunosorbent assay (ELISA) intended for the qualitative detection of human IgG antibodies to type 2 herpes simplex virus (HSV) in human serum. The test is indicated for sexually active individuals and expectant mothers as an aid in the presumptive diagnosis of HSV-2 infection. The predictive value of a positive or negative result depends on the prevalence of HSV-2 infection in the population and the pre-test likelihood of HSV-2 infection.

The test is not FDA cleared for screening blood or plasma donors. The performance of this assay has not been established for immunocompromised patients, pediatric patients or matrices other than human serum.

Predicate Device:

A commercial, legally marketed HSV 1 and 2 Immunoblot IgG test.

Table 1. Device Comparison

Characteristic	SeraQuest HSV 2 IgG	HSV 1 and 2 Immunoblot IgG
Technology	Enzyme Immunoassay	Immunoblot
Intended Use	Intended Use: For In Vitro Diagnostic Use Only. The SeraQuest HSV Type 2 Specific IgG assay is an	For In Vitro Diagnostic Use. For qualitatively detecting the presence or absence of human IgG class antibodies to

	enzyme-linked immunosorbent assay (ELISA) intended for the qualitative detection of human IgG antibodies to type 2 herpes simplex virus (HSV) in human serum. The test is indicated for sexually active individuals and expectant mothers as an aid in the presumptive diagnosis of HSV-2 infection. The predictive value of a positive or negative result depends on the prevalence of HSV-2 infection in the population and the pre-test likelihood of HSV-2 infection. The test is not FDA cleared for screening blood or plasma donors. The performance of this assay has not been established for immunocompromised patients, pediatric patients or matrices other than human serum.	HSV-1 and HSV-2 in human sera. The test is indicated for testing sexually active adults or expectant mothers for aiding in the presumptive diagnosis of HSV-1 and HSV-2 infection. The predictive value of a positive or negative result depends on the population's prevalence and the pre-test likelihood of HSV-1 or HSV-2 infection. The performance of this assay has not been established for use in a pediatric population, for neonatal screening, for testing immuno-compromised patients, for use by a point of care facility, or for use with automated equipment.
Solid Phase	Polystyrene Microwells	Nitrocellulose membrane
Antigen	Purified HSV gG 2	Recombinant HSV gG1 and HSV gG2
Incubation Periods	Three	Three
Sample Dilution	1:51	1:101
Sample Volume	100 µL	2000 µL
Sample Incubation Duration	30 minutes	60 minutes
Incubation Temperature	Room Temperature	Room Temperature
Washing Steps	Two	Four
Cycles per Washing Step	Four	Three
Enzyme-Labeled Conjugate	Alkaline Phosphatase Conjugated Goat Anti-Human IgG	Alkaline Phosphatase Conjugated Goat Anti-Human IgG

Conjugate Volume	100 µL	2000 µL
Conjugate Incubation	30 minutes	30 minutes
Enzyme Substrate	p-nitrophenyl phosphate	Bromo-chloro-indolyl phosphate and nitro blue tetrazolium
Substrate Volume	100 µL	2000 µL
Substrate Incubation	30 minutes	5 to 30 minutes
Stop Reagent	0.5 M Trisodium Phosphate	DI Water
Stop Reagent Volume	100 µL	5 X 2000 µL
Drying Step	None	Air dry, 10 minutes
Readout	Spectrophotometric 405 nm	Visual

Summary of Performance Testing

1. Precision Testing

Six serum specimens (2 negative, and 4 positive) and the SeraQuest HSV Type 2 Specific IgG Positive and Negative Controls, were assayed in triplicate, on three separate occasions, at Quest International and at two external independent laboratories. The results are summarized below in Table 2.

Table 2.

Results of Intra-assay, Inter-assay and Inter-laboratory Precision Tests Performed at Quest International and at Two External, Independent Laboratories. The Means, Standard Deviations and Coefficients of Variation were Calculated from the SeraQuest Index values.

Name of Analyte Panel Member	Sample N	Mean Index	Intra-assay		Inter-assay		Inter-laboratory		Total	
			SD	CV%	SD	CV%	SD	CV%	SD	CV%
SeraQuest Positive Serum Control	27	2.0	0.20	9.9	0.27	13.7	0.31	15.4	0.26	13.0
SeraQuest Negative Serum Control	27	0.3	0.04	13.5	0.08	21.2	0.15	48.2	0.09	27.6
Negative Sample # 1	27	0.3	0.08	26.7	0.10	31.2	0.11	35.9	0.10	31.3
Negative Sample # 2	27	0.4	0.04	9.6	0.06	14.4	0.09	21.6	0.06	15.2
Positive Sample # 1	27	1.8	0.15	8.3	0.19	10.7	0.23	12.4	0.19	10.5
Positive Sample # 2	27	2.1	0.12	5.7	0.18	8.8	0.21	10.0	0.17	8.1
Positive Sample # 3	27	2.8	0.16	5.6	0.25	9.0	0.32	11.4	0.24	8.7
Positive Sample # 4	27	3.5	0.27	7.8	0.38	10.7	0.42	11.9	0.36	10.1

2. Specificity Testing

A cross-reactivity study was performed to determine if samples from various disease states and other potentially cross-reacting agents interfere with the test results. The samples were determined to be positive for IgG antibodies directed against taxonomically related viruses and other related pathogens by other legally marketed devices. Human Papilloma Virus, Chlamydia trachomitis, and Neisseria gonorrhea samples were from individual patients with confirmed sexually transmitted infections. The samples were also tested for Type 2 HSV antibody by another legally marketed device. Only those samples that tested negative for Type 2 HSV antibody by the legally marketed device were included in the study. The results of this study are shown below in Table 3.

Table 3. Results of SeraQuest HSV Type 2 Specific IgG Tests of Samples Which Tested Positive for Antibodies Directed Against Taxonomically Related Viruses and Other Viruses and Pathogens but Negative for Type 2 HSV by Other Legally Marketed Devices.

Samples	Number of Samples	Number of Samples Testing Positive in the SeraQuest HSV 2 Type Specific IgG Test
HSV 1 IgG	9	0/9
CMV IgG	11	0/11
VZV EBNA IgG	14	0/14
VZV VCA IgG	17	0/17
VZV IgG	21	0/21
Measles IgG	19	0/19
Rubella IgG	18	0/18
Toxoplasma IgG	6	0/6
Syphilis IgG	4	0/4
Human Papilloma Virus	7	0/7
Chlamydia trachomitis	8	1/8
Neisseria gonorrhea	7	0/7

3. Interference Testing

The effects of icterus, hemolysis, hyperglycemia, hyperlipidemia and hyperproteinemia on the test results were examined. Samples that were negative, weakly positive and moderately positive for antibodies to Type 2 HSV were tested with and without the addition of elevated levels of the following potential interfering substances: hemoglobin 18 g/dL, glucose 800 mg dL, cholesterol 2,720 mg/dL, globulin 28 g/dL, unconjugated bilirubin 20 mg/dL, conjugated bilirubin 20 mg/dL, human albumin 12 g/dL and ascorbic acid 3mg/dL.

No significant interference was observed in the presence of abnormally elevated levels of the potentially interfering substances tested, however the use of grossly hemolyzed, icteric or lipemic samples, as well as samples containing particulate matter or exhibiting obvious microbial contamination is not recommended and they should not be tested.

4. Comparison With The Predicate Device

One hundred and sixty-four serum samples, from sexually active adults that were submitted for HSV serology to a clinical laboratory in the Southeastern United States, were prospectively collected, masked, archived, and tested at Quest International, Inc. using the SeraQuest HSV

Type 2 Specific IgG test and a commercial HSV 2 Immunoblot test. The results of this comparative test are shown in Table 4 below.

Table 4

Relative Sensitivity and Specificity of the SeraQuest HSV 2 Type Specific IgG Test, in Comparison with an HSV 2 Immunoblot Test, in Parallel Tests of 164 Sexually Active Adults Whose Sera Had Been Submitted for Herpes Simplex Virus Serology.

SeraQuest HSV 2 Type Specific IgG Result						
	Positive	Equivocal	Negative		% Agreement*	95% C.I.*
HSV 2 Immunoblot Result						
Positive	56	0	5	Sensitivity	91.8	82.2 to 96.5
Negative	6	0	97	Specificity	94.2	87.9 to 97.3

Two hundred and forty-two serum samples, from expectant mothers, that were submitted for HSV serology to clinical laboratories in the Northeastern and Southeastern United States, were prospectively collected, masked, archived, and tested at Quest International, Inc. using the SeraQuest HSV Type 2 Specific IgG test and a legally marketed, HSV 2 Immunoblot test. One hundred and ninety-eight (82%) of the specimens were obtained during the first trimester, nineteen (8%) during the second trimester and twenty-five (10%) during the third trimester of pregnancy. The results of this comparative test are shown in Table 5 below.

Table 5

Sensitivity and Specificity of the SeraQuest HSV 2 Type Specific IgG Test, in Comparison with a Commercial HSV 2 Immunoblot Test, in Parallel Tests of 242 Expectant Mothers Whose Sera Had Been Submitted for Herpes Simplex Virus Serology.

Seraquest HSV 2 Type Specific IgG Result						
	Positive	Equivocal	Negative		% Agreement*	95% C.I.*
HSV 2 Immunoblot Result						
Positive	87	0	1	Sensitivity	98.9	93.8 to 99.8
Negative	0	1	153	Specificity	99.4	96.4 to 99.9

CDC Panel Results

The following information was obtained with the Centers for Disease Control and Prevention (CDC) serum panel for HSV serology assays, which was tested in-house by the SeraQuest HSV Type 2 Specific IgG test. The results are presented as a means to convey further information on

the performance of this assay with a masked, well characterized serum panel. This does not imply an endorsement by the CDC.

Percent Agreement with the CDC Panel

The panel consists of 30 HSV-2 IgG positive and 70 HSV-2 IgG negative samples. The SeraQuest HSV Type 2 Specific IgG test demonstrated 100% total agreement with the CDC consensus results. The results of this study are shown below in Table 7.

Table 7 SeraQuest HSV Type 2 Specific IgG Results Obtained with the CDC HSV Panel of 100 Sera

		SeraQuest HSV Type 2 Specific IgG			
		Positive	Equivocal	Negative	Total
CDC HSV 2 Result	Positive	30	0	0	30
	Negative	0	0	70	70
	Total	30	0	70	100