June 13, 2019

Quest International, Inc.
Steve Andrus
Quality Assurance Manager
1935 SW Martin Highway
Palm City, Florida 34990

Re: K181514
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: May 13, 2019
Received: May 15, 2019

Dear Steve Andrus:

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. 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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K181514

Device Name

SeraQuest HSV Type 2 Specific IgG

Indications for Use *(Describe)*
Intended Use

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.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Applicant: Awareness Technology Inc. / Quest International, Inc.
1935 SW Martin Highway
Palm City, FL 34990

Contact Person: Steve Andrus
Quality Assurance Manager
Phone: 772.283.6540 ext. 220
Fax: 772.283.8020
Email: sandrus@awaretech.com

Trade Name: SeraQuest® HSV Type 2 Specific IgG
Common Name: Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-2

Product Nomenclature	510(k) Number	Class	Product Code	Regulation Number	Review Panel
Enzyme Linked Immunosorbent Assay, Herpes Simplex Virus, Hsv-2	K181514	II	MYF	866.3305	Microbiology

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:
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:
SeraQuest® HSV Type 2 Specific IgG assay 510(k) 152353 manual method.

Predicate Comparison

All reagents, controls, calibrators, and critical procedural steps of the manual and the automatic methods for the SeraQuest HSV Type 2 Specific IgG assay are identical.

A comparison of the automatic device test procedure and the predicate device test procedure appears below:

Characteristic	SeraQuest ® HSV Type 2 Specific IgG assay performed by Manual Method (Predicate)	SeraQuest ® HSV Type 2 Specific IgG assay performed by ChemWell® Automated Analyzer
Submission number	K152353	K181514
Technology	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use	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.	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.
Solid Phase	Polystyrene Microwells	Polystyrene Microwells
Antigen	Purified HSV gG 2	Purified HSV gG 2
Incubation Periods	Three 30 minutes	Three 30 minutes
Sample Dilution	1:51	1:51
Sample Volume	100 µL	100 µL
Sample Incubation Duration	30 minutes	30 minutes
Incubation Temperature	Room Temperature	Room Temperature
Washing Steps	Two	Two
Cycles per Washing Step	Four	Four
Enzyme-Labeled Conjugate	Alkaline Phosphatase Conjugated Goat Anti-Human IgG	Alkaline Phosphatase Conjugated Goat Anti-Human IgG
Conjugate Volume	100 µL	100 µL
Conjugate Incubation	30 minutes	30 minutes
Enzyme Substrate	p-nitrophenyl phosphate	p-nitrophenyl phosphate
Substrate Volume	100 µL	100 µL
Substrate Incubation	30 minutes	30 minutes
Stop Reagent	0.5 M Trisodium Phosphate	0.5 M Trisodium Phosphate
Stop Reagent Volume	100 µL	100 µL
Drying Step	None	None
Readout	Spectrophotometric 405 nm	Spectrophotometric 405 nm

Summary of Performance Testing

Precision Study

A precision study with a panel of samples was run on the current manual procedure and on the ChemWell® Automated Analyzer. The panel consists of samples in the following categories: true negative, high negative, low positive, and moderate positive. Precision evaluation of within-run, between-run, between-day, and within lab precision was determined over the duration of 12 days, with 2 runs per day, and 2 replicates of each sample per run and 1 replicate per control per run. Data analysis includes calculation of the mean, standard deviation and %CV for each panel.

The precision results for HSV Type 2 IgG Method: Manual

			Within-Run		Between-Run		Between-Day		Within Lab	
Sample Description	N	Mean Value	SD	%CV	SD	%CV	SD	CV%	SD	CV%
Negative Control	24	0.18	-	-	0.03	15.75%	0.03	13.84%	0.04	20.96%
Positive Control	24	2.66	-	-	0.11	3.98%	0.04	1.55%	0.11	4.27%
True Negative	48	0.19	0.03	13.48%	0.03	13.48%	0.01	3.32%	0.04	19.35%
High Negative	48	0.76	0.03	4.24%	0.04	5.02%	0.02	2.76%	0.05	6.54%
Low Positive	48	1.56	0.04	2.61%	0.04	2.61%	0.06	3.83%	0.08	5.32%
Moderate Positive	48	2.86	0.06	1.95%	0.09	3.23%	0.09	3.11%	0.14	4.89%

The precision results for HSV Type 2 IgG Method: ChemWell® Automated Analyzer

			Within Run		Between-Run		Between-Day		Within Lab	
Sample Description	N	Mean Value	SD	%CV	SD	CV%	SD	CV%	SD	CV%
Negative Control	24	0.13	-	-	0.05	35.34%	0.01	6.74%	0.05	35.97%
Positive Control	24	2.52	-	-	0.11	4.36%	0.01	0.35%	0.11	4.37%
True Negative	48	0.13	0.04	31.61%	0.01	11.17%	0.02	12.38%	0.05	35.74%
High Negative	48	0.75	0.05	7.20%	0.05	6.09%	0.02	3.31%	0.07	9.99%
Low Positve	48	1.59	0.07	4.54%	0.09	5.37%	0.05	3.35%	0.12	7.79%
Moderate Positive	48	2.68	0.08	3.14%	0.10	3.57%	0.07	2.78%	0.15	5.51%

Method Comparison Study

The percent agreement between the manual and the ChemWell® Automated Analyzer was evaluated by testing a total of 226 samples with both methods. Samples were developed from remnants of patient samples and samples from vendors. Additional samples were prepared by spiking negative samples with positive samples or dilution with diluent reagent to span the range of the assay measuring interval. All samples were tested with the assay performed with - manual method and the ChemWell Automated Analyzer.

The concordance analysis for the manual and the ChemWell Automated Analyzer are summarized in the table below.

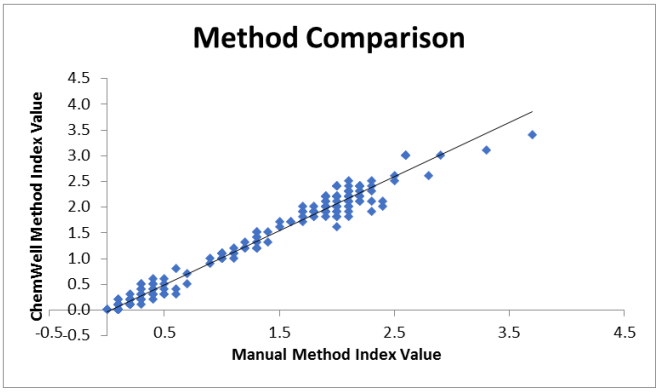
Percent Agreement (PPA) and Negative Percent Agreement (NPA) between the SeraQuest HSV Type 2 Specific IgG assay manual method and the ChemWell Automated Analyzer

		Manual Method			
		Positive	**Equivocal**	**Negative**	**Total**
ChemWell Automated Method	**Positive**	125	0	1	**126**
	Equivocal	0	0	0	**0**
	Negative	0	0	100	**100**
	Total	**125**	**0**	**101**	**226**

	Absolute	**Relative**	**Two-sided 95% CI**
Positive Percent Agreement (PPA)	125/125	100%	97.02% to 100%
Negative Percent Agreement (NPA)	100/101	99.01%	94.60% to 99.83%

Ordinary Linear Regression - All Points

Parameter	**Slope**	**Intercept**	**R^2**	**Range**	**n**
HSV-2	1.0526	-0.0364	0.9770	0-3.7	226



Conclusions

Analysis of the performance for assay on the manual method and the ChemWell Automated Analyzer in this 510(k) including data collected for precision and correlation demonstrates that the SeraQuest ® HSV Type 2 Specific IgG assay performed by ChemWell® Automated Analyzer is substantially equivalent to the predicate device (manual method).