APPENDIX 3. (revised)

Quest International, Inc., 1938 N.E. 148th Terrace, N. Miami, FL 33181

K990977

OCT 6 1999

510(k) SUMMARY

Applicant: Quest International, Inc.
1938 N.E. 148th Terrace
North Miami, FL 33181

Registration No. 1061839

Contact Person: Robert A. Cort, V.P., Quality Assurance

Telephone: (305) 948-8788

Telefax: (305) 948-4876

Manufacturing Site: Same as above

Device: SeraQuest® EB VCA IgM

Device Name: Epstein-Barr virus serological reagents (21CFR § 866.3235)

Device Classification: Class I (general controls)

Description:

The SeraQuest EB VCA IgM test is a solid-phase enzyme immunoassay (EIA), which is performed in microwells, at room temperature, in three thirty minute incubations. It has been developed to detect IgM antibodies which are directed against Epstein-Barr virus capsid antigen, in human serum.

The Calibrators in the SeraQuest EB VCA IgM test set have been assigned Index values based on an in-house standard. Test results are reported as Index values.

Principle:

Diluted samples are incubated in wells coated with Epstein-Barr virus capsid antigen. *Absorbents have been included in the Diluent to neutralize the affects of rheumatoid factor and IgG antibody.* Antibodies directed against Epstein-Barr virus capsid antigen (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme-labeled antibodies to human IgM) is added and incubated. If IgM antibodies to Epstein-Barr virus capsid antigen are present, the conjugate will be immobilized in the wells. Residual conjugate is eliminated by washing and draining, and the enzyme substrate is added and incubated. In the presence of the enzyme, the substrate is converted to a yellow end-product which is read photometrically at 405 nm.

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Intended Use:

For the qualitative detection of IgM antibodies to Epstein-Barr (EB), viral capsid antigen (VCA) in human serum by enzyme immunoassay, as an aid in differentiating active or recent Epstein-Barr virus infection from past infection. For in vitro diagnostic use only.

Predicate Device:

The SeraQuest EB VCA IgM test is substantially equivalent in intended use and performance, to the Gull Laboratories' EBV IgM ELISA test, Gull Laboratories, Inc., Salt Lake City, Utah.

Summary of technological characteristics:

Characteristic	SeraQuest EB VCA IgM	Gull Laboratories ' EBV IgM ELISA
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	The detection of IgM antibodies against Epstein-Barr virus capsid antigen in human serum.	The detection of IgM antibodies against Epstein-Barr virus capsid antigen in human serum.
Solid Phase:	Plastic Microwell	Plastic Microwell
Antigen :	Recombinant p18	Purified gp 125
Number of Incubation Periods:	Three	Three
Sample Dilution:	1:51	1:11
Sample Incubation Duration:	30 minutes	30 minutes
Incubation Temperature:	Room temperature	37 ºC.
Ezyme-labeled Conjugate:		
Antibody	Goat anti-human IgM	Goat anti-human IgM
Label	Alkaline phosphatase	Alkaline phosphatase
Conjugate Volume:	100 µl	100 µl
Conjugate Incubation Duration:	30 minutes	30 minutes
Substrate:	p-Nitrophenyl phosphate	p-Nitrophenyl phosphate

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Subtrate Volume:	100 µl	100 µl
Substrate Incubation Duration:	30 minutes	30 minutes
Stop Reagent:	0.5 M Trisodium phosphate	1.5 N NaOH
Stop Reagent Volume:	100 µl	100 µl
Readout:	Spectrophotometric 405 nm	Spectrophotometric 405 nm

Summary of Clinical Testing:

Of the 157 specimens tested, 26 were positive, and 121 were negative in both the SeraQuest and Gull Laboratories' tests (please see Table 1). Of the 10 remaining specimens, 3 specimens which were negative by the Gull test, were positive by the SeraQuest test, and 5 specimens which were positive by the Gull test, were negative by the SeraQuest test. Two specimens gave equivocal results in the SeraQuest test and were negative by the Gull test.

Table 1.

Results of Tests of 157 Archival Patient Specimens Tested at SeraQuest, Miami, FL, Using the SeraQuest EB VCA IgM Test and Gull Laboratories' EBV VCA IgM EIA Test.

Gull LABS EBV VCA IgM	SeraQuest EB VCA IgM Positive	Negative	Equivocal	Total
Positive	26	5	0	31
Negative	3	121	2	126
Equivocal	0	0	0	0
Total	29	126	2	157

Overall agreement [(TP + TN) / (TP + TN + FP + FN)] = 94.8 % *
95 % CI = 94.8 to 98.3 % √

* Excluding equivocal results
√ Calculated by the normal method.

Reference: Gardner, M.J. and Altman, D.G., Confidence Intervals Rather Than Hypothesis Testing. Brit. Med. J., 292: 746-750, 1986.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 6 1999

Mr. Robert A. Cort
Vice President, Quality Assurance
Quest International, Inc.
1938 N.E. 148th Terrace
North Miami, Florida 33181

Re: K990977
Trade Name: SeraQuest EB VCA IgM
Regulatory Class: I
Product Code: LJN
Dated: July 30, 1999
Received: August 2, 1999

Dear Mr. Cort:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Quest International, Inc., 1938 N.E. 148th Terrace, N. Miami, FL 33181

APPENDIX 6 (revised)

510(k) Number (if known): K990977

Device Name: SeraQuest EB VCA IgM

Indications For Use:

1. For the qualitative detection of IgM antibodies to Epstein-Barr (EB), viral capsid antigen (VCA) in human serum by enzyme immunoassay, as an aid in differentiating active or recent Epstein-Barr virus infection from past infection.

2. For in vitro diagnostic use only.

3. A positive result is presumptive for the detection of anti-Epstein-Barr virus IgM antibodies and presumptive for the diagnosis of acute or recent Epstein-Barr virus infection.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990977

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)