

APR 24 1998

510(k) SUMMARY

K 980391

**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® Anti-dsDNA

**Device Name:** Anti-nuclear antibody immunological test system (21CFR § 866.5100)  
Systemic lupus erythematosus immunological test system  
(21CFR § 866.5620)

**Device Classification:** Class II (performance standards)

**Description:**

The SeraQuest Anti-dsDNA 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 IgG antibodies which are directed against dsDNA, in human serum.

The Calibrators in the SeraQuest Anti-dsDNA test set have been assigned IU/ml values which are traceable to the WHO First International Standard for Anti-Double-Stranded DNA, Wo-80, and Index values which based on an in-house standard anti-dsDNA serum. Test results are reported as IU/ml or as Index values.

**Principle:**

Diluted samples are incubated in wells coated with dsDNA antigen. Antibodies against ds DNA (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme-labeled antibodies to human IgG) is added and incubated. If IgG antibodies to DSDNA 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.

**Intended Use:**

For the qualitative, semi-quantitative and quantitative detection of human IgG antibodies to dsDNA in human serum by enzyme immunoassay, as an aid in the diagnosis systemic lupus erythematosus (SLE). For manual use, or for use with the HyPrep System Plus. For In Vitro Diagnostic Use Only.

**Predicate Device:**

The SeraQuest Anti-dsDNA test is substantially equivalent in intended use and performance, to the Shield DIASTAT Anti-dsDNA kit, Shield Diagnostics, Dundee, UK.

**Summary of technological characteristics:**

<u>Characteristic</u>	<u>SeraQuest Anti-dsDNA</u>	<u>Shield Anti-dsDNA</u>
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	The detection of IgG antibodies against dsDNA in human serum.	The detection of IgG & IgM antibodies against dsDNA in human serum.
Solid Phase:	Plastic Microwell	Plastic Microwell
Antigen:	Calf Thymus DNA	Calf Thymus DNA
Number of Incubation Periods:	Three	Three
Sample Dilution:	1:50	1:100
Sample Incubation Duration:	30 minutes	60 minutes
Incubation Temperature:	Room temperature	Room temperature
Ezyme-labeled Conjugate:		
Antibody	Goat anti-human IgG	Goat anti-human IgG & IgM
Enzyme	Alkaline phosphatase	Alkaline phosphatase
Conjugate Volume:	100 µl	100 µl
Conjugate Incubation Duration:	30 minutes	30 minutes
Substrate:	p-Nitrophenyl phosphate	phenolphthalein monophosphate

Substrate Volume:	100 µl	100 µl
Substrate Incubation Duration:	30 minutes	30 minutes
Stop Reagent:	0.5 M Trisodium phosphate	Sodium Hydroxide
Stop Reagent Volume:	100 µl	100 µl
Readout:	Spectrophotometric 405 nm	Spectrophotometric 550 nm

Summary of Clinical Testing:

Of 215 specimens tested, 64 were positive, 126 were negative and 1 was equivocal in both the SeraQuest and Shield tests (Table 1 below). Of the 25 remaining specimens: 5 specimens were equivocal in the SeraQuest test and of these, 2 were positive and 3 were negative by the Shield test; 11 specimens were equivocal by the Shield test and of these, 4 were positive and 7 were negative by the SeraQuest test; 3 specimens which were positive by the SeraQuest test were negative by the Shield test, and 5 specimens which were positive by the Shield test were negative by the SeraQuest test.

TABLE 1.

RESULTS OF SeraQuest ANTI-dsDNA ASSAYS AND SHIELD DIASTAT ANTI-dsDNA ASSAYS OF 215 SERUM SPECIMENS, PERFORMED AT QUEST INTERNATIONAL, INC., MIAMI, FL.

	SeraQuest ANTI-dsDNA				
SHIELD DIASTAT ANTI-dsDNA	Positive	Equivocal	Negative	%	95% CI <sup>√</sup>
Positive	64 {36}	2	5	Relative sensitivity*	92.8 86.6 to 98.9
Equivocal	4 {2}	1	7 {1}		
Negative	3 {1}	3 {2}	126 {8}	Relative specificity*	97.7 95.1 to 100
				Overall agreement*	96.0 93.2 to 98.7

{ } Number of patients with clinically diagnosed SLE.

\* Excluding equivocal results.

√ Calculated by the normal method.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 24 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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

Re: K980391/S1  
Trade Name: SeraQuest® Anti-dsDNA  
Regulatory Class: II  
Product Code: LRM  
Dated: April 14, 1998  
Received: April 17, 1998

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 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 requirement, 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.

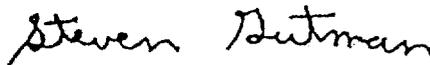
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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

Enclosure

APPENDIX 6 (revised 4/10/98)

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510(k) Number (if known): K980391

Device Name: SeraQuest Anti-dsDNA

Indications For Use:

1. For in vitro diagnostic use only.
2. For the qualitative, semi-quantitative and quantitative detection of IgG antibodies to dsDNA in human serum by enzyme immunoassay.
3. For use as an aid in the diagnosis of systemic lupus erythematosus (SLE).
4. For manual use, or for use with the HyPrep System Plus semi-automated fluid handler.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number K980391

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)