

K980810

MAY 12 1998

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® Anti-SSA

Device Name: Antinuclear antibody immunological test system (21CFR § 866.5100)

Device Classification: Class II (performance standards)

Description:

The SeraQuest Anti-SSA 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 SSA nuclear antigen (Anti-SSA) , in human serum.

The Calibrators in the SeraQuest Anti-SSA 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 SSA antigen. Antibodies against SSA (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 SSA 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 and semi-quantitative detection of human antibodies to SSA nuclear antigen in human serum by enzyme immunoassay. For use as an aid in the diagnosis of systemic rheumatic

disease, particularly Sjogren's Syndrome. For manual use, or for use with the HyPrep System Plus. For In Vitro Diagnostic Use Only.

Predicate Device:

The SeraQuest Anti-SSA test is substantially equivalent in intended use and performance, to the Shield Diastat Anti-SSA test, Shield Diagnostics, Dundee, DD2 1SW.

Summary of technological characteristics:

| <u>Characteristic</u> | <u>SeraQuest Anti-SSA</u> | <u>Shield Diastat Anti-SSA</u> |
|--------------------------------|---|---|
| Description: | Enzyme Immunoassay | Enzyme Immunoassay |
| Intended Use: | The detection of antibodies against SSA in human serum. | The detection of antibodies against SSA in human serum. |
| Solid Phase: | Plastic Microwell | Plastic Microwell |
| Antigen Source: | Calf Thymus | Calf Thymus |
| Number of Incubation Periods: | Three | Three |
| Sample Dilution: | 1:50 | 1:500 |
| 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 |
| 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 540-565 nm |

Summary of Clinical Testing:

Of the 288 specimens tested, 74 were positive, and 200 were negative in both the SeraQuest and Shield tests (please see Table C-3). Of the remaining specimens, 10 specimens which were negative by the Shield test, 8 were positive and 2 equivocal by the SeraQuest test; 4 specimen which were positive by the Shield test, one was equivocal and 3 negative in the SeraQuest test. Refer to table 1 below.

TABLE 1.

RESULTS OF SeraQuest Anti-SSA ASSAYS AND SHIELD Anti-SSA ASSAYS OF 288 SERUM SPECIMENS.

| Shields ANTI-SSA | SeraQuest ANTI-SSA | | | | % 95 % CI* |
|---------------------|--------------------|-----------|----------|---|--|
| | Positive | Equivocal | Negative | | |
| Positive | 74 | 1 | 3 | Relative sensitivity√ | 96.1 91.8 to 100 |
| Negative | 8 | 2 | 200 | Relative specificity√ Overall agreement√ | 96.1 93.5 to 98.8 96.1 93.9 to 98.4 |

√ Excluding equivocal results.
* Calculated by the exact method.
** 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.



MAY 12 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Robert A. Cort
Vice President, Quality Assurance
QUEST INTERNATIONAL, INC.
1938 N.E. 148th Terrace
North Miami, FL 33181

Re: K980810
Trade Name: SeraQuest® Anti-SSA
Regulatory Class: II
Product Code: LJM
Dated: April 28, 1998
Received: April 28, 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 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.

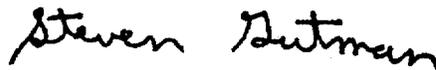
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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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 (301) 443-6597, or at its internet address "<http://www.fda.gov/cdrh/dsma/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

APPENDIX 8

Page 1 of 1

510(k) Number (if known): _____

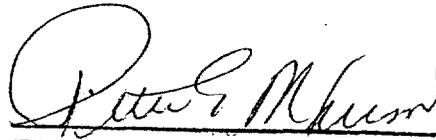
Device Name: SeraQuest Anti-SSA

Indications For Use:

1. For in vitro diagnostic use only.
2. For the qualitative and semi-quantitative detection of IgG antibodies to SSA in human serum by enzyme immunoassay.
3. For use as an aid in the diagnosis of systemic rheumatic disease, particularly Sjogren's Syndrome.
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 1980810

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)