510(k) SUMMARY K023593

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

FEB 06 2003

Registration No. 1061839

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

Telephone: (305) 948-8788

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Manufacturing Site: Same as above

Device: SeraQuest® Anti-Thyroid Peroxidase

Device Name: Anti-Thyroid Peroxidase, Multiple autoantibodies immunological test system (21CFR § 866.~~5660~~ 5870)

Device Classification: Class II (Performance Standards)

Description:

The SeraQuest Anti-Thyroid Peroxidase test is a solid-phase enzyme immunoassay (EIA), which is performed in microwells, at room temperature, in three thirty minutes incubations. It has been developed to detect IgG antibodies which are directed against Thyroid Peroxidase, in human serum.

The Calibrators in the SeraQuest Anti-Thyroid Peroxidase test kit have been assigned values based on the NIBSC standard. Test results are reported as international units per milliliter (IU/mL).

Principle:

Diluted samples are incubated in wells coated with thyroid peroxidase antigen. Antibodies directed against this antigen (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 thyroglobulin 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.

Intended Use:

Intended Use: The Anti-Thyroid Peroxidase test is intended for the quantative detection of human IgG antibodies to thyroid peroxidase antigen, in human serum by enzyme immunoassay. The presence of anti-thyroid peroxidase antibodies can be used with other serological tests and clinical findings to aid

diagnosing individuals with Autoimmune Thyroditis and Grave's Disease. For In Vitro Diagnostic Use Only.

Predicate Device:

The SeraQuest Anti-Thyroid Peroxidase test is substantially equivalent in intended use and performance, to the Pharmcia Varelisa TPO Antibodies, Freiburg, Germany.

Summary of Technological Characteristics:

Characteristic	SeraQuest Anti-Thyroid Peroxidase Test	Pharmacia Varelisa TPO Antibodies Test
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	The detection of IgG antibodies against thyroid peroxidase in human serum.	The detection of IgG antibodies against thyroid peroxidase in human serum.
Solid Phase: Polystyrene Microwell	Polystyrene Microwell	
Antigen :	Purified thyroid peroxidase (human thyroid)	Recombinant thyroid peroxidase
Number of Incubation Periods:	Three	Three
Sample Dilution:	1:51	1:101
Sample Incubation Duration:	30 minutes	30 minutes
Incubation Temperature:	Room temperature	Room temperature
Ezyme-labeled Conjugate:		
Antibody	Goat anti-human IgG	Goat anti-human IgG
Enzyme	Alkaline phosphatase	Horse Radish Peroxidase
Conjugate Volume:	100 µl	100 µl
Conjugate Incubation Duration:	30 minutes	30 minutes
Substrate:	p-Nitrophenyl phosphate	TMB

Subtrate Volume:	100 µl	100 µl
Substrate Incubation Duration:	30 minutes	10 minutes
Stop Reagent:	0.5 M Trisodium phosphate	0.34 M Sulfuric acid
Stop Reagent Volume:	100 µl	50 µl
Readout:	Spectrophotometric	Spectrophotometric
Wavelength:	405 nm	450 nm
Reference Wavelength:	620 nm	
Normalization:	Standard Curve	Standard Curve
Reporting Unit:	IU / mL	IU / mL

Summary of Clinical Testing:

Experimental Procedure

To challenge the cutoff values, 141 serum specimens were tested at Quest International, Inc., concurrently by the SeraQuest Anti-Thyroid Peroxidase test, and the Varelisa TPO Antibodies test (Pharmacia & Upjohn). The assays were performed and interpreted according to the instructions in the manufacturer's package inserts.

Results and Conclusion

The qualitative agreement between the SeraQuest and the Pharmacia tests is shown in Table 1.

Of the 141 specimens tested, 22 were positive, 107 were negative and 1 was equivocal in both the SeraQuest and Varelisa tests (please see Table C-3). Of the 11 specimens remaining, 1 specimen which was negative by the Varelisa test, was positive by the SeraQuest test; 1 specimen which was negative in the SeraQuest test, was equivocal by the Varelisa test; 7 which were equivocal in the SeraQuest test, 2 were positive and 5 negative in the Varelisa test; 2 which were equivocal in the Varelisa test were positive in the SeraQuest test.

Excluding the equivocal results, the sensitivity of the SeraQuest Anti-Thyroid Peroxidase (TPO) test relative to the Varelisa test was 100%, or 99.9% to 100% (95% C.I.); the specificity was 99.1%, or 97.7% to 100% (95% C.I.); respectively. The overall agreement was 99.2%, or 97.3% to 100% (95% C.I.) (please see Table C-3).

ABLE 1.

RESULTS OF SeraQuest ANTI-THYROGLOBULIN ASSAYS AND PHARMACIA ANTI-THYROGLOBULIN ASSAYS ON 141 SERUM SPECIMENS.

	SeraQuest					
PHARMACIA	POS	EQU	NEG		%	95% C.I.**
POS	22	2	0	Relative Sensitivity*	100	99.9-100
EQU	2	1	1			
NEG	1	5	107	Relative Specificity*	99.1	97.7-100
				Overall Agreement*	99.2	97.3-100

*** Excluding equivocal results.**
**** 95%Confidence Interval calculated by the normal method.**

The specimen that gave a discordant result was tested by a second legally marketed device, the Scimedix Anti-Thyroid Peroxidase Test, Scimedix Corp., Denville, New Jersey. The sample gave a positive result with the Scimedix test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 0 6 2003

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

Re: k023593
Trade/Device Name: SeraQuest Anti Thyroid Peroxidase (TPO)
Regulation Number: 21 CFR 866.5870
Regulation Name: Thyroid Autoantibody Immunological Test System
Regulatory Class: Class II
Product Code: JZO
Dated: December 23, 2002
Received: December 24, 2002

Dear Mr. Cort:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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 Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

APPENDIX 6

510(k) Number (if known): K023593

Device Name: SeraQuest Anti-Thyroid Peroxidase (TPO)

Indications For Use:

1. For the quantitative detection of IgG antibodies to thyroid peroxidase in human serum by enzyme immunoassay.

2. The SeraQuest Anti-thyroid peroxidase test can be used with other serological tests and clinical findings, to aid in the diagnosis of thyroid diseases such as Autoimmune Thyroiditis and Graves' disease.

3. For in vitro diagnostic use only.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

J P Reeves for S. Bautista
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023593

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

(Optional Format 1-2-96)