JUL 2 5 2003

510k Summary

Date of Summary: June 26, 2003

Product Name:

ThyroTest

Sponsor:

ThyroTec, Inc.
1801 Horseshoe Pike, Suite 1
Brandywine Business Center
Honey Brook, PA 19344
Tel: 610.942.8970
Fax: 610.942.8973

Manufacturer:

VEDA LAB
Rue del'Expansion
ZAT du Londeau
CERISE-B.P. 181 61006 Alencon
Cedex France

Correspondent:

MDC Associates
Fran White
Regulatory Consultant
163 Cabot Street
Beverly, MA 01915
Tel: 978.927.3808
Fax: 978.927.1308
Email: fran@mdcassoc.com

Substantially Equivalent Devices:

Product: ThyroChek One-Step Whole Blood Rapid TSH Assay

Manufacturer: Little Nell Labs, Inc.
K990658

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Thyrotest
Additional Information

INTENDED USE:

The ThyroTest is a whole blood, qualitative assay for the detection of an increased level of TSH (Thyroid Stimulating Hormone). An increase level of TSH can be an indication of primary hypothyroidism. For professional use only.

SUMMARY OF TECHNOLOGY:

Purified Polyclonal anti TSH antibodies are passively absorbed on the absorbent membrane. Anti-TSH monoclonal antibodies are absorbed on colloidal gold and then mixed in a protein matrix to obtain the final dye conjugate.

Once applied to the specimen well, blood sample undergoes vertical capillary filtration through the porous filtration system. The blood cells are retained in the top layers while the liquid phase (plasma) reaches the bottom membrane layer. The buffer, when applied to the specimen well, flows along the bottom membrane layer, mixes with plasma and migrates horizontally along the test membrane. If TSH is present in the sample in concentrations at or above the detection level, labeled antibody-dye conjugates binds to it, forming an antigen-antibody-dye complex. This complex is then captured by antibody immobilized in the Test Zone ("T") of the membrane, producing a visible pink-rose color band on the membrane. A similarly colored conjugate is captured by a parallel immunochemical reaction in the Control Zone ("C") of the membrane. A distinctive control band is the marker of proper test performance.

PERFORMANCE DATA:

A three center clinical trial was done to compare the performance of ThyroTest to an approved FDA TSH method, the Abbott AxSYM. The following is a summary of the data generated.

Total Participants	**289**
Total ThyroTest Positives	**33**
True Positives (TP)	**26**
False Positives (FP)	**7**
Total Negatives	**256**
True Negatives	**250**
False Negatives	**6**

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Performance Characteristics

	AxSYM Positive	AxSYM Negative	Total
ThyroTest Positive	26	7	33
ThyroTest Negative	6	250	256
Total	32	257	289

Positive Agreement	81.25%
Negative Agreement	97.28%
Correlation	95.50%

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STATEMENT OF SAFETY AND EFFICACY:

The ThyroTest when compared to an FDA cleared TSH method demonstrated a correlation when compared to another FDA cleared method of 96% with a positive agreement of 81% and a negative agreement of 97%.

These data clearly demonstrate the safety and efficacy of the ThyroTest and further confirm the accuracy, sensitivity and specificity of this product when compared to a substantially equivalent device currently being sold for professional use. A trained Laboratory Technician performed testing in a CLIA registered laboratory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 25 2003

ThyroTec, Inc.
c/o Ms. Fran White
Regulatory Consultant
MDC Associates
163 Cabot Street
Beverly, MA 01915

Re: k030912
Trade/Device Name: ThyroTest
Regulation Number: 21 CFR 862.1690
Regulation Name: Thyroid stimulating hormone test system
Regulatory Class: Class II
Product Code: JLW
Dated: June 26, 2003
Received: June 30, 2003

Dear Ms. White:

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

510k Submission
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510(k) Number: K030912
Device Name: ThyroTest

Indication for Use:

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Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)