510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K030912

B. Analyte:
Thyroid Stimulating Hormone

C. Type of Test:
Qualitative

D. Applicant:
ThyroTec, Inc.

E. Proprietary and Established Names:
ThyroTest

F. Regulatory Information:

1. Regulation section:
   21 CFR 862.1690

2. Classification:
   Class II

3. Product Code:
   JLW

4. Panel:
   75

G. Intended Use:

1. Intended use(s):
   The ThyroTest whole blood, one-step, rapid TSH assay for hypothyroidism screening in adults is a lateral flow chromatographic immunoassay for the qualitative determination of human thyroid stimulating hormone (TSH) in whole blood.

2. Indication(s) for 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.

3. Special condition for use statement(s):
   This device is intended for use in hospitals, doctor's offices/physician's office laboratories (POL), and clinics.

4. Special instrument Requirements:
   Not applicable

H. Device Description:

The kit consists of the following:

- Test Cassette (with mouse monoclonal and goat anti-mouse IgG antibodies), sealed in a foil pouch.
- Pipette (sealed in foil pouch with Test Cassette)
- Test buffer (Phosphate buffered saline – 0.1 M, pH 8.2)
- Package insert

The test cassette incorporates multi-layer filtration and sandwich immunoassay systems in a single module. It allows for both the pretreatment of the whole blood sample and the immunochromatrographic detection assay to be performed in one step.

The blood (once applied to the sample well) undergoes vertical capillary filtration through the porous filtration system. The red blood cells are retained in the top layers while the liquid phase (plasma) reaches the bottom membrane layer.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   ThyroChek One-Step Whole Blood Rapid TSH Assay

2. Predicate K number(s):
   K990658

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Qualitative detection of TSH in whole blood	Qualitative detection of TSH in whole blood
Principle	Lateral flow two-site immunochromatographic assay	Lateral flow two-site immunochromatographic assay
Sensitivity	5 µIU/mL	5 µIU/mL
Differences		
Item	**Device**	**Predicate**
Intended Use	Hospitals, doctor's offices/POLs, and clinics	Ambulatory setting

Reagents	Mouse and goat antibodies	Mouse and sheep antibodies

J. Standard/Guidance Document Referenced (if applicable):
Not applicable

K. Test Principle:
ThyroTest is a lateral flow two-site immunochromatographic assay.

L. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:
Nine known positive samples, with AxSYM values ranging between 5.90 and 33.78 μIU/mL, were tested in triplicate on the ThyroTest device. ThyroTest correctly identified all of them as positive.

b. Linearity/assay reportable range:
Not applicable

c. Traceability (controls, calibrators, or method):
Not applicable

d. Detection limit:
To demonstrate the limits of detection, spiked samples (ranging from 2.50 to 7.50 μIU/mL according to the AxSYM) were each tested 10 times on the ThyroTest. The ThyroTest correctly identified the negative and positive samples.

e. Analytical specificity:
Other hormones and commonly encountered substances were spiked into negative and positive TSH samples and tested for interference. 200,000 mIU/mL hCG, 2,000 mIU/mL FSH, 500 mIU/mL LH, prescription drugs, OTC drugs, and chemical analytes were evaluated. The ThyroTest correctly identified the negative and positive samples.

Additionally, hematocrit (ranging from 20-50) was evaluated and had no effect on the negative and positive samples.

f. Assay cut-off:
See Detection limit above.

2. Comparison studies:

a. Method comparison with predicate device:
The ThyroTest was compared to the Abbott AxSYM Immunochemistry Analyzer. Testing was performed at three sites

(WA, TN, and NY) using blood from randomly selected patients (males and females in the approximate age range of 48-52 years). A trained laboratory technician performed the rapid ThyroTest with capillary whole blood. Venous blood was drawn and forwarded to a reference laboratory, where the Abbott AxSYM quantitative TSH was performed using serum.

A total of 289 results comparing the ThyroTest to the Abbott AxSYM test were obtained. The range of AxSYM values for the three sites were <0.002-19.95 µIU/mL, 0.0130-100 µIU/mL, and 0.0150-31.73 µIU/mL. Seven (7) samples were positive on the ThyroTest and negative on the AxSYM test, and six (6) samples were negative on the ThyroTest and positive on the AxSYM test. The results yielded 81.25% positive agreement, 97.28% negative agreement, and an overall correlation of 95.50%.

b. Matrix comparison:
Not applicable

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable

   b. Clinical specificity:
   Not applicable

   c. Other clinical supportive data (when a and b are not applicable):
   Not applicable

4. Clinical cut-off:
   Not applicable

5. Expected values/Reference range:
   The expected values were based on the Mayo Medical Laboratories published age-stratified normal ranges.

M. Conclusion:

The ThyroTest device is very similar in intended use, principle, and methodology to the ThyroChek One-Step Whole Blood Rapid TSH Assay. The ThyroTest is also similar in performance to the Abbott AxSYM TSH, as evidenced by the data provided. In addition to the performance data, the revised labeling is adequate and conforms to 21 CFR 809.10. Therefore, I recommend a substantial equivalence determination for the ThyroTest.