

JUN 2 1999

15. SMDA Summary

K 990658

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. This new immunometric assay device is a single-use Class II medical device for professional use that is designed to indicate whether a capillary or venous blood sample contains TSH in a concentration ≥ 5 micro IU/ml. The intended use, technical characteristics, efficacy, and safety of this new device are substantially equivalent at detecting TSH ≥ 5 micro IU/ml to a number of other TSH immunoassays that have been commercially available both before and after 1978, and Little Nell Labs believes that demonstration of substantial equivalence to a legally marketed predicate device in accordance with section 510(k) has been demonstrated.

This document contains the results of a number of validation studies which compare the performance of the whole blood rapid TSH assay at detecting TSH ≥ 5 micro IU/ml to that of predicate medical devices, including second (K853717) and third (K930007) generation TSH immunoassays, and to a serum-based lateral flow immunochromatographic assay (K960195). The results obtained are as follows:

1. Quantitative recovery data demonstrates analytic sensitivity between 4.06-5.62 micro IU/ml.
2. Serial dilution data demonstrates analytic sensitivity between 4.57-5.87 micro IU/ml.
3. Parallelism demonstrates:
 - a. functional sensitivity of 5.0 micro IU/ml.
 - b. % agreement in identifying specimens with TSH ≥ 5 microIU/ml compared to predicate second / third generation TSH assays = 99%
 - c. % agreement in identifying specimens with TSH ≥ 5 microIU/ml compared to predicate serum-based one-step rapid TSH assay = 99%.
4. Replicated testing with 10 aliquots at 5 TSH concentrations showed no intra-assay variation (coefficient of variation = 0).
5. Specificity and Interference. Assay performance is not affected by:
 - a. hCG in concentrations up to 82,500 mIU/ml
 - b. LH / FSH in concentrations > 25 mIU/ml
 - c. hematocrit between 14-65%
 - d. azotemia with BUN up to 70 mg% and creatinine up to 8.6 mg%
 - e. hyperglycemia with blood sugars up to 707 mg%
 - f. hyperlipidemia with serum triglycerides up to 844 mg%.

This 510(k) Summary Statement was prepared by J. Ehrenkranz, M.D., Little Nell Labs, Inc. 1676 E. Sopris Creek Road, Basalt, Co. 81621, 970-927-5253, on 21 May 1999.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 1999

Joel R.L. Ehrenkranz, M.D.
Little Nell Labs Inc./Third World Diagnostics, Inc.
1676 East Sopris Creek Road
Basalt, CO 81621

Re: K990658
Trade Name: ThyroChek One-Step Whole Blood Rapid TSH Assay
Regulatory Class: II
Product Code: JLW
Dated: May 07, 1999
Received: May 13, 1999

Dear Dr. Ehrenkranz:

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 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 (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 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.

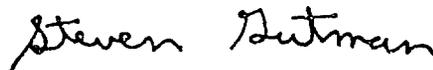
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

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

510(k) Number (if known): K990658

Device Name: ThyroChek one-step whole blood
rapid TSH assay

Indications For Use:

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990658

The ThyroChek whole blood, rapid TSH assay is a visual, non-instrument, qualitative, solid-phase, lateral flow, two-site immunochromatographic assay for identifying capillary or venous blood samples that contain TSH > 5 microlU/ml. The test is intended for use as an in-vitro diagnostic device by medical professionals to screen for primary hypothyroidism. It is not indicated for use as a screening method for neonatal hypothyroidism.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)