

ATTACHMENT 3**510(k) SUMMARY**

[Refer to 21 CFR §807.92]

CASCO•NERL Diagnostics

Submitted by:

500 Riverside Industrial Parkway
Portland, ME 04103-1418
(207)-878-7550

Contact Person:

Karen Hickey

Date Prepared:

June 10, 1999

Proprietary Name:

DOCUMENT Thyroid CAL•VER™

Common Name:

Calibration Verification Quality Control Material

Classification Name:

Control, Multianalyte Assayed
(21 CFR §862.1660)

Predicate Device:

DOCUMENT Serum Multianalyte Calibration Verification Test Set
510(k) #K950469

Description of the Device:

DOCUMENT Thyroid CAL • VER contains assayed solutions of the following analytes: Thyroxine (T4), Triiodothyronine (T3) and Thyroid Stimulating Hormone (TSH) in a serum matrix. Multiple levels are provided to establish the linear relationship between theoretical operation and actual performance of each chemistry. d Thyroid CAL • VER contains 8 levels, 1 bottle per level, 5.0 milliliters per bottle.

Intended Use of the Device:

d Thyroid CAL • VER contains assayed solutions for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range on immunochemistry systems and clinical chemistry systems for the following analytes: Thyroxine (T4), Triiodothyronine (T3) and Thyroid Stimulating Hormone (TSH). This product is not intended for use as a calibration material on instrument systems or as a routine quality control material.

Technological Characteristics:

Many inspection agencies require the documentation of periodic linearity, calibration verification of reportable range studies on procedures in the clinical laboratory. d Thyroid CAL • VER will assist in this process when used as instructed. In addition, d Thyroid CAL • VER will provide valuable assistance when troubleshooting chemistry systems, reagent problems and calibration anomalies.

Performance Characteristics and Data

d Thyroid CAL • VER consists of 8 levels which cover the reportable range of instrumentation on the market. Targets cover the clinical reference range for the analytes present. This product has a 12-month shelf life at frozen temperatures (-10 to -20°C).



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL 23 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Karen Hickey
Director, Quality Assurance
and Regulatory Affairs
CASCO NERL Diagnostics Corporation
500 Riverside Industrial Parkway
Portland, Maine 04103-1418

Re: K992034
Trade Name: DOCUMENT Thyroid CAL•VER™
Regulatory Class: I
Product Code: JJY
Dated: June 15, 1999
Received: June 16, 1999

Dear Ms. Hickey:

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.

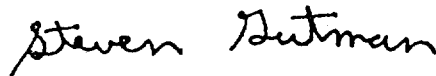
Page 2

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, flowing 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

III. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K 992034

Device name: **DOCUMENT Thyroid CAL•VER™**

Indications for Use:

DOCUMENT Thyroid **CAL • VER** contains assayed solutions intended for *in vitro* diagnostic use in the quantitative determination of linearity, calibration verification and verification of reportable range on immunochemistry systems and clinical chemistry systems for the following analytes: Thyroxine (T4), Triiodothyronine (T3) and Thyroid Stimulating Hormone (TSH).

☒ Prescription Use

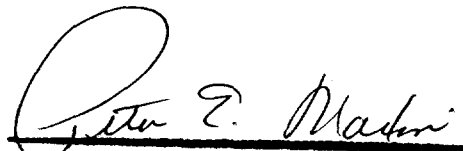
(Per 21 CFR 801.109)

OR

☐ Over-The-Counter-Use

(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

992034