



NOV 20 1997

K973276

EG&G WALLAC INC.

9238 GAITHER RD.
GAITHERSBURG, MD 20877 U.S.A.
TELEPHONE: (301) 963-3200
1-800-838-6692
FAX: (301) 963-7780

Re: **510(k) Summary**

Date: August 26, 1997

Submitter: EG&G Wallac Inc.
9238 Gaither Road
Gaithersburg, MD 20877

Telephone: (301)963-3200

Fax: (301)963-7780

Contact: Paul D. Davis

Trade Name: AutoDELFIA™ Neonatal hTSH L Kit

Common Name: Neonatal hTSH Liquid Time-Resolved Fluoroimmunoassay

Classification Name: Thyroid Stimulating Hormone Test System

Predicate Device: AutoDELFIA™ Neonatal hTSH Kit

Device Description:

The AutoDELFIA™ Neonatal hTSH L assay is a solid phase, two-site fluoroimmunometric assay based on the direct sandwich technique in which two monoclonal antibodies are directed against separate antigenic determinants on the hTSH molecule. Standards, controls and test specimen containing hTSH are reacted simultaneously with immobilised monoclonal antibodies in assay buffer. The assay buffer elutes hTSH from the dried blood spots on the filter paper discs. The complete assay requires only one incubation step. Enhancement solution dissociates europium ions from the labelled antibody into solution where they form highly fluorescent chelates with components of the enhancement solution. The fluorescence in each well is then measured. The fluorescence of each sample is proportional to the concentration of hTSH in the sample.

510(k) Summary Cont'd

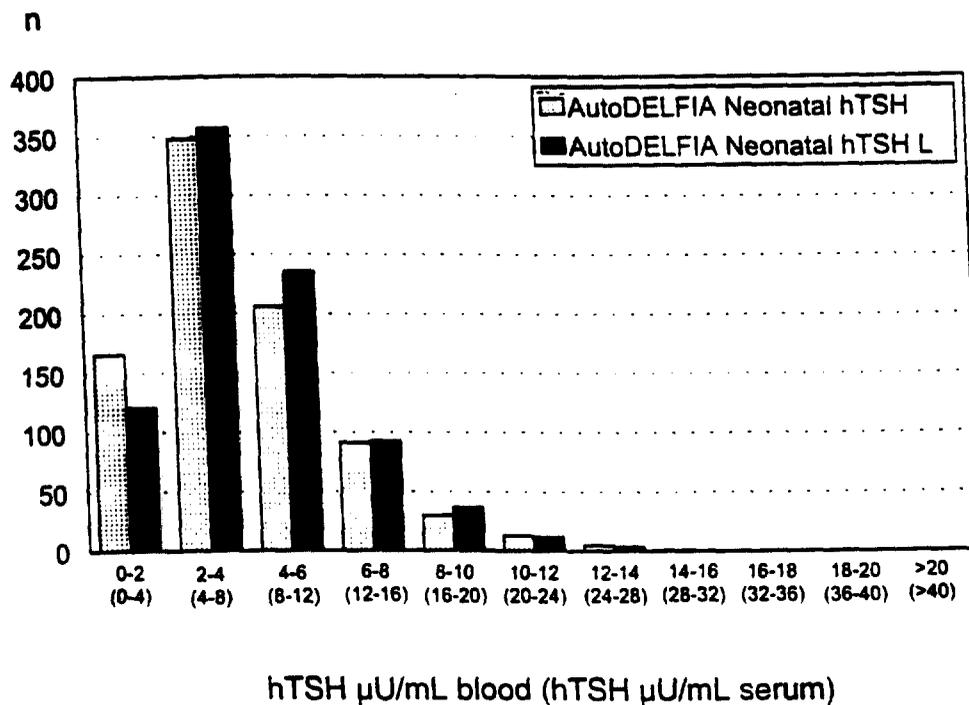
Intended Use:

The kit is intended for the quantitative determination of thyrotropin in blood specimens dried on filter paper as an aid in screening newborns for congenital hypothyroidism, using the 1235 AutoDELFIA™ automatic immunoassay system

Equivalence Comparison:

The AutoDELFIA™ Neonatal hTSH L kit was compared to the AutoDELFIA™ Neonatal hTSH kit and found to be substantially equivalent. The major difference between the kits is the matrix of the standards and controls. The predicate device utilizes a paper matrix while the new device utilizes a liquid matrix. In addition, a medium control has been added.

hTSH concentrations were measured in 860 newborns with the AutoDELFIA™ Neonatal hTSH kit and with the AutoDELFIA™ Neonatal hTSH L kit. The reference range when measured with the AutoDELFIA™ Neonatal hTSH kit was 0.55 - 14.9 $\mu\text{U}/\text{mL}$ blood, with a mean value of 3.96 $\mu\text{U}/\text{mL}$ blood. The reference range when measured with the AutoDELFIA™ Neonatal hTSH L kit was 0.69 - 12.7 $\mu\text{U}/\text{mL}$ blood, with a mean value of 4.13 $\mu\text{U}/\text{mL}$ blood. The frequency distributions are shown in the following figure:





NOV 20 1997

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Paul D. Davis
Manager of Quality and Regulatory Affairs
EG&G Wallac Inc.
9238 Gaither Road
Gaithersburg, Maryland 20877

Re: K973276
AutoDELFIATM Neonatal hTSH L Kit
Regulatory Class: II
Product Code: JLW
Dated: November 4, 1997
Received: November 7, 1997

Dear Mr. Davis:

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 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 (Pre-market 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.

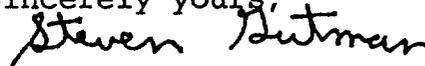
Page 2

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/dsmamain.html>".

Sincerely yours,



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

2. Device Name [807.87(a)]

A. Trade Name:

AutoDELFIATM Neonatal hTSH L Kit

B. Common Name:

Neonatal hTSH Liquid Time-Resolved Fluoroimmunoassay

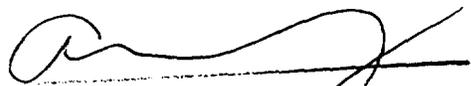
C. Classification Name:

Thyroid Stimulating Hormone Test System

D. Indications for use:

This kit is intended for the quantitative determination of thyrotropin in blood specimens dried on filter paper as an aid in screening newborns for congenital (neonatal) hypothyroidism, using the 1235 AutoDELFIATM automatic immunoassay system.

✓ Prescription Use


510(k) [unclear] Devices
K97326.7