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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

Assigned 510(k) Number: K003414

Date of Summary Preparation: October 25, 2000

Distributor:
Pharmacia & Upjohn
Diagnostics Division, US Operation
7425-248-1
7000 Portage Road
Kalamazoo, MI 49001

Manufacturer:
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Kalamazoo, MI 49001
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Device Name: Varelisa® TG (Thyroglobulin) Antibodies

Common Name: Thyroid autoantibody immunological test system.

Classification:

Product Name	Product Code	Class	CFR
Varelisa® TG Antibodies	82JZO	II	866.5870

Substantial Equivalence to:

elias™ TG Antibodies

Intended Use Statement:

The Varelisa® TG (Thyroglobulin) Antibodies EIA kit is designed for the quantitative and qualitative determination of thyroglobulin antibodies in serum or plasma to aid in the diagnosis of thyroid diseases such as Autoimmune Thyroiditis and Graves' Disease.

General Description of the Device

The Varelisa TG Antibodies is an indirect noncompetitive enzyme immunoassay for the quantitative and qualitative determination of thyroglobulin antibodies in serum or plasma.

The determination of TG antibodies is of central importance for the clinical diagnosis of thyroid diseases. The presence of TG antibodies suggests the possibility of autoimmune diseases such as Autoimmune Thyroiditis and Graves' Disease.

Varelisa® TG Antibodies Test Principle

Varelisa TG Antibodies is an indirect noncompetitive enzyme immunoassay. The wells of a microplate are coated with human thyroglobulin antigen. Antibodies specific for TG present in a patient sample bind to this antigen.

In a second step an enzyme labeled second antibody (Conjugate) binds to the antigen-antibody complex which leads to the formation of an enzyme labeled antigen-antibody sandwich complex.

The enzyme labeled antigen-antibody complex converts the added substrate to form a colored solution. The rate of color formation from the chromogen is a function of the amount of Conjugate complexed with the bound antibody and thus is proportional to the initial concentration of the respective antibodies in the patient sample.

Device Comparison and Clinical Performance:

Elias TGAb Assay (the original/predicate device) and Varelisa® TG Antibodies Assay (the new/modified device) both are indirect noncompetitive enzyme immunoassays for the determination of anti-thyroid antibodies in serum or plasma to aid in the diagnosis of thyroid diseases such as autoimmune thyroiditis and Grave's Disease.

The essential differences between both assays are the changed calibration / measuring range and the update in the assay evaluation (additional qualitative evaluation and inclusion of an equivocal range).

The most important common features between old and new version are the nature of the antigen determining the specificity of the assay (Thyroglobulin purified from human thyroid tissue) and the standardization against the Human anti-Thyroglobulin serum, 1st International Reference Preparation, NIBSC Code 65/93.

In addition to the common standardization assuring comparability of the assay results between old and new version of the assay, the correct clinical performance of the Varelisa® TG Antibodies Assay is supported by a data set including

- results obtained for clinically defined positive and negative sera
- results obtained for External Quality Assessment sera
- results obtained for samples from apparently healthy subjects (normal population).

The data show that the assay performs as expected from the medical literature.

In summary, all available data support that the new/modified device, Varelisa TG Antibodies Assay is substantially equivalent to the predicate/original device, elias TGAb Assay and that the new/modified device performs according to state-of-the-art expectations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 27 2000

Ms. Karen E. Matis
Manager, Regulatory Affairs
and Quality Management
Pharmacia & Upjohn
Diagnostics Division, US Operations
5094 St. Andrews Drive
Westerville, Ohio 43082

Re: K003414
Trade Name: Varelisa® TG (Thyroglobulin) Antibodies
Regulatory Class: II
Product Code: JZO
Dated: November 1, 2000
Received: November 2, 2000

Dear Ms. Matis:

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.

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" (21CFR 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,

Steven Gutman

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

Varelisa® TG Antibodies - Device Modification
510(k) Submission
Section 1. Indications For Use Statement

510(k) Number: K003414

Device Name: **Varelisa® TG (Thyroglobulin) Antibodies**

The Varelisa TG (Thyroglobulin) Antibodies EIA kit is designed for the quantitative and qualitative determination of thyroglobulin antibodies in serum or plasma to aid in the diagnosis of thyroid diseases such as Autoimmune Thyroiditis and Graves' Disease.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Peter E. Maxim

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K003414