MAY 1 1998

510 (k) Summary
Safety and Effectiveness

K980206

This summary of safety and effectiveness information has been prepared in accordance with the requirements of SMDA 1990 and 21 CFR Part 807.92.

Name: **Address:**	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Telephone Number: **Facsimile Number:**	(213) 776-0180 (213) 776-0204
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Date of Preparation:	April 17, 1998
Device Name: **Trade:**	IMMULITE Anti-TG Ab
Catalog Number:	LKTGZ (50 tests), LKTG1 (100 tests), LKTG5 (500 tests)
Common:	Reagent system for the determination of Anti-TG Ab in serum, EDTA, heparinized, and citrate plasma.
Manufacturer:	EURO/DPC Ltd. (Manufacturing under a Quality System- ISO 9002/EN29002/BS 5750)
Sole U.S. Importer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597
Establishment Registration Number:	EURO/DPC: Not Applicable DPC: 2017183

Substantially Equivalent Predicate Device:

ORGenTec Anti-TG PIN Immuno Assay (K950090) Manufactured by ORGenTec, and distributed in the USA by ALPCO, Windham, NH

Description of Device:

IMMULITE® Anti-TG Ab is a clinical device for use with the IMMULITE® Automated Immunoassay Analyzer.

Intended Use of the Device:

IMMULITE® Anti-TG Ab is a solid-phase, two-step chemiluminescent enzyme immunometric assay for use with the IMMULITE® Automated Immunoassay Analyzer and designed for the quantitative measurement of antibodies against thyroglobulin (TG) in serum, EDTA, heparinized, and citrate plasma. It is intended strictly for *in vitro* diagnostic use as an aid in the clinical diagnosis of thyroid diseases.

Performance Equivalence:

Diagnostic Products Corporation (DPC) asserts that the IMMULITE® Anti-TG Ab produces substantially equivalent results to other commercially marketed Anti-TG assays, such as the ORGenTec anti-TG PIN Immuno Assay. Each product is intended strictly for *in vitro* diagnostic use to aid in the clinical diagnosis of thyroid diseases.

Summary and Explanation of the Test:

Thyroglobulin is produced only by the thyroid gland and is a major component of the thyroid follicular colloid. The thyroid hormones thyroxine (T4) and 3,5,3' - triodothyronine (T3) are synthesized from thyroglobulin.

Autoantibodies to thyroglobulin (TG autoantibodies) are often present in patients with autoimmune thyroid disease. Approximately 10 percent of healthy individuals have TG autoantibodies at low levels; higher concentrations are found in 30 and 85 percent of patients with Graves' disease and Hashimoto's thyroiditis, respectively. Elevated levels of antibodies to thyroid peroxidase (TPO autoantibodies) occur more frequently than high anti-TG levels in these diseases, however; anti-TG determinations therefore do not seem to add to the diagnostic information provided by anti-TPO results.

TG autoantibody measurements are most useful for evaluating samples submitted for thyroglobulin measurements because TG autoantibodies can interfere with both competitive immunoassays and immunometric assays for thyroglobulin.

Technological Comparison to Predicate:

IMMULITE® Anti-TG Ab is a solid-phase, two-step chemiluminescent enzyme immunometric assay. The solid-phase, a polystyrene bead enclosed within an IMMULITE Test Unit, is coated with highly purified thyroglobulin.

The pre-diluted patient sample and a buffer matrix are simultaneously introduced into the Test Unit, and incubated for 30 minutes at 37° C with intermittent agitation. During this time, TG autoantibodies in the sample bind to the TG-coated bead. The serum/buffer mixture is then removed by a centrifugal wash.

An alkaline phosphatase-labeled anti-human-IgG antibody is introduced, and the Test Unit is incubated for another 30-minute cycle. The unbound enzyme conjugate is removed by a centrifugal wash, after which substrate is added, and the Test Unit is incubated for a further 10 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield a stable intermediate. The continuous production of this intermediate results in the sustained emission of light, thus improving precision by providing a window for multiple readings. The bound enzyme conjugate-and thus also the photon output, as measured by the luminometer- is proportional to the concentration of TG autoantibodies in the sample.

The **ORGenTec Anti-TG PIN Immuno Assay** is an indirect solid phase enzyme immunometric assay (ELISA) based on coated micropins corresponding to a microplate format. Designed for the quantitative measurement of IgG class autoantibodies directed against human thyroglobulin. The Pin assay employs a unique antigen coated micropin technology. Coated PinStrips act as the transferable solid phase. Seven pre-scored breaking lines allow strips to be used in a 2, 4, 6, 8, or 10 row strip assay, while a complete plate provides for 96 determinations, ideal for smaller runs as well as economical batch processing. The assay takes place in three reaction phases:

Phase 1: Standards, controls and patient samples are pipetted into the wells of the first microplate. Micropins, coated with highly purified antigen, are immersed into the samples allowing any antibody present to bind to the pin surface. After a 10 minute incubation, the pins are removed, non-reactive components are washed away by dipping the pins into wash buffer.

Phase 2: The pins are then immersed into a second microplate containing enzyme conjugate, which recognizes the autoantibodies bound to the immobilized antigens. Any conjugate not specifically bound, is washed away after a 10 minute incubation.

Phase 3: The pins are then immersed into the wells of a third microplate containing chromogenic substrate solution of OPD (o-phenylenediamine) which changes from colorless to yellow during a 5 minute incubation. Color development is stopped by dispensing 3M sulfuric acid. The amount of color is directly proportional to the concentration of IgG present in the original sample. Optical density is read with a microplate reader at 490 nm. Bichromatic measurement is recommended with a 650 nm reference.

Method Comparison:

The IMMULITE® Anti-TG Ab procedure was compared to the ORGenTec anti-TG PIN Immunoassay procedure on 137 patient samples, with anti-TG Ab concentrations ranging from non-detectable to >3,000 IU/mL. The agreement, relative sensitivity and relative specificity were 89%, 97% and 86%, respectively.

Conclusion:

The data presented in this summary of safety and effectiveness is the data that the Food and Drug Administration used in granting DPC substantial equivalence for IMMULITE Anti-TG Ab.

Edward M. Levine

4/17/98

Edward M. Levine, Ph.D.
Director of Clinical Affairs

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 1998

Edward M. Levine, Ph.D.
Director of Clinical Affairs
Diagnostic Products Corporation
5700 West 96th Street
Los Angeles, California 90045-5597

Re: K980206/S1
Trade Name: IMMULITE Anti-TG Ab
Regulatory Class: II
Product Code: JZO
Dated: April 8, 1998
Received: April 9, 1998

Dear Dr. Levine:

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 (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 requirement, 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.

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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

510(k) Number (if known): K980206

Device Name: **IMMULITE® Anti-TG Ab**

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maheux

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

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)