K023304

DEC 0 9 2002

510 (k) Summary
Safety and Effectiveness

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, CA 90045
Telephone Number: **Facsimile Number:**	(310) 645-8200 (310) 645-9999
Contact Person:	Edward M. Levine, Ph.D. Director of Clinical Affairs
Date of Preparation:	October 1, 2002
Device Name:	
Trade:	IMMULITE®/IMMULITE®1000 Calcitonin IMMULITE® 2000 Calcitonin
Catalog Number:	LKCL L2KCL
CFR:	A calcitonin test system is a device intended to measure the thyroid hormone calcitonin (thyrocalcitonin) levels in plasma and serum. Calcitonin measurements are used in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism (excessive activity of the parathyroid gland).
Common:	Reagent system for the determination of calcitonin in serum.
Classification:	Class II device, JKR (21 CFR 862.1140)
Panel:	Clinical Chemistry
CLIA Complexity Category:	We believe the category to be moderate, based on previous classification of analogous tests.
Manufacturer:	Diagnostic Products Corporation (DPC) 5700 West 96th Street Los Angeles, CA 90045-5597

Establishment Registration #: DPC's establishment Registration No. is 2017183

Substantially Equivalent Predicate Device: Nichols Advantage™ Calcitonin (K964635)

Description of Device: IMMULITE/IMMULITE 1000 Calcitonin and IMMULITE 2000 Calcitonin are solid-phase, chemiluminescent enzyme immunoassays for use with their respective IMMULITE/IMMULITE 1000 and IMMULITE 2000 Automated Analyzers.

Intended Use of the Device: IMMULITE/IMMULITE 1000 Calcitonin and IMMULITE 2000 Calcitonin are for *in vitro* diagnostic use for the quantitative measurement of calcitonin in human serum, as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism.

Technology:

This section does not contain any new information for a reviewer who is familiar with the DPC IMMULITE System based upon the review of previous IMMULITE and IMMULITE 2000 assay submissions.

IMMULITE/IMMULITE 1000 Calcitonin is a solid-phase, enzyme-labeled, two-site chemiluminescent immunometric assay. The solid-phase, a polystyrene bead enclosed within an IMMULITE/IMMULITE 1000 Test Unit, is coated with a monoclonal murine antibody specific for calcitonin.

While the patient serum sample and alkaline phosphatase-conjugated to polyclonal goat anti-calcitonin are incubated for approximately 30 minutes at 37°C in the Test Unit with intermittent agitation, calcitonin in the sample is bound to form an antibody sandwich complex. Unbound enzyme conjugate is then 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 an unstable 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 complex - and thus also the photon output, as measured by the luminometer - is proportional to the concentration of calcitonin in the sample.

IMMULITE 2000 Calcitonin is a solid-phase, enzyme-labeled, two-site chemiluminescent immunometric assay. The solid-phase, a polystyrene bead, is coated with a monoclonal murine antibody specific for calcitonin.

While the patient serum sample and alkaline phosphatase-conjugated to polyclonal goat anti-calcitonin are incubated for approximately 30 minutes at 37°C in the Reaction Tube with intermittent agitation, calcitonin in the sample is bound to form an antibody sandwich complex. Unbound enzyme conjugate is then removed by a centrifugal wash, after which substrate is added and the Reaction Tube is incubated for a further 5 minutes.

The chemiluminescent substrate, a phosphate ester of adamantyl dioxetane, undergoes hydrolysis in the presence of alkaline phosphatase to yield an unstable 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 complex - and thus also the photon output, as measured by the luminometer - is proportional to the concentration of calcitonin in the sample.

Nichols Advantage Calcitonin assay is a two-site chemiluminescence immunoassay for the measurement of calcitonin in human serum. It utilizes two mouse monoclonal antibodies to human calcitonin. One of the mouse monoclonal antibodies is labeled with acridinium ester for detection, while a second mouse monoclonal antibody is coupled to biotin. Calcitonin is "sandwiched" between these antibodies.

The sample containing calcitonin is incubated simultaneously with both antibodies. The formation of a soluble sandwich complex occurs only in the presence of calcitonin molecules, which bridge the two antibodies. Therefore, only peptides that bridge these two antibodies can be quantitated.

After an initial incubation period, steptavidin coated magnetic particles are added to the reaction mixture and a second incubation follows. This allows for a highly specific and efficient means of binding the sandwich complex to the solid phase via the high affinity interaction between biotin and streptavidin. Free labeled antibody is separated from the labeled antibody bound to the magnetic particles by aspiration of the reaction mixture and subsequent washing. The wells containing the washed magnetic particles are transported into the system luminometer, which automatically injects Trigger 1 and Trigger 2, initiating the chemiluminescence reaction. The light is quantitated by the luminometer and expressed as RLU. The amount of bound labeled antibody is directly proportional to the concentration of calcitonin in the sample.

Performance Equivalence:

Diagnostic Products Corporation asserts that the IMMULITE/IMMULITE 1000 Calcitonin and IMMULITE 2000 Calcitonin produce substantially equivalent results to other commercially marketed Calcitonin assays, such as Nichols Advantage™ Calcitonin used with the Nichols Advantage™ Specialty System. Each product is designed for the quantitative measurement of calcitonin in human serum. Each product is intended strictly for *in vitro* diagnostic use as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism.

Method Comparison

The IMMULITE/IMMULITE 1000 Calcitonin procedure was compared to a commercially available assay (Nichols Advantage) on 53 patient samples, with calcitonin concentrations ranging up to approximately 1,200 pg/mL. Linear regression analysis yielded the following statistics.

(IMMULITE/IMMULITE 1000) = 0.71 (Nichols) + 4.2 pg/mL r = 0.990

Means: 155 pg/mL (IMMULITE/IMMULITE 1000)
212 pg/mL (Nichols)

The IMMULITE 2000 Calcitonin procedure was compared to a commercially available assay (Nichols Advantage) on 67 patient samples, with calcitonin concentrations ranging up to approximately 1,500 pg/mL. Linear regression analysis yielded the following statistics.

(IMMULITE 2000) = 0.81 (Nichols) - 0.4 pg/mL r = 0.982

Means: 193 pg/mL (IMMULITE 2000)
239 pg/mL (Nichols)

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®/IMMULITE® 1000 Calcitonin and IMMULITE® 2000 Calcitonin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 0 9 2002

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

Re: k023304
Trade/Device Name: IMMULITE®/ IMMULITE® 1000 Calcitonin
IMMULITE® 2000 Calcitonin
Regulation Number: 21 CFR 862.1140
Regulation Name: Calcitonin test system
Regulatory Class: Class II
Product Code: JKR; JJY
Dated: October 1, 2002
Received: October 3, 2002

Dear Dr. Levine

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K023304
Device Name: IMMULITE®/IMMULITE® 1000 Calcitonin
IMMULITE® 2000 Calcitonin

Indications For Use:

IMMULITE/IMMULITE 1000 Calcitonin
For *in vitro* diagnostic use with the IMMULITE/IMMULITE 1000 Analyzer – for the quantitative measurement of calcitonin (thyrocalcitonin) in human serum, as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism.

IMMULITE 2000 Calcitonin
For *in vitro* diagnostic use with the IMMULITE 2000 Analyzer – for the quantitative measurement of calcitonin (thyrocalcitonin) in human serum, as an aid in the diagnosis and treatment of diseases involving the thyroid and parathyroid glands, including carcinoma and hyperparathyroidism.

(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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023304