NOV 2 0 2001

K013566

510(k) Summary of 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, California 90045-5597
Telephone Number: **Facsimile Number:**	(310) 645-8200 (310) 645-9999
Contact Person:	Edward M. Levine, Ph.D. Director, Clinical Affairs
Date of Preparation:	October 25, 2001
Device Name:	
Trade:	IMMULITE® Intact PTH IMMULITE® 2000 Intact PTH
Catalog Number:	LKPP1 (100 tests), LKPP5 (500 tests) L2KPP2 (200 tests), L2KPP6 (600 tests)
CFR:	A parathyroid hormone test system is a device intended to measure the levels of parathyroid hormone in serum and plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism.
Common:	Reagent system for the determination of parathyroid hormone in plasma and serum.
Classification:	Class II device, CEW (21CFR 862.1545)
Panel:	Clinical Chemistry
CLIA Complexity Category:	We believe the category to be moderate, based on previous classification of analogous tests.
Manufacturer:	Diagnostic Products Corporation 5700 West 96th Street Los Angeles, California 90045-5597

Establishment Registration Number: DPC's Registration Number is 2017183

Substantially Equivalent Predicate Device: IMMULITE Intact PTH (K011505)
IMMULITE 2000 Intact PTH (K011505)

Description of Device: IMMULITE Intact PTH and IMMULITE 2000 Intact PTH are solid phase, chemiluminescent enzyme immunometric assays for use with their respective IMMULITE and IMMULITE 2000 Automated Analyzers.

Intended Use of the Device:

IMMULITE Intact PTH and IMMULITE 2000 Intact PTH are solid-phase, two-site chemiluminescent enzyme immunometric assays for use with their respective IMMULITE® and IMMULITE 2000 Automated Analyzers and are designed for the quantitative measurement of intact parathyroid hormone (parathyrin, PTH) in EDTA plasma or serum. It is intended strictly for *in vitro* diagnostic use as an aid in the differential diagnosis of hypercalcemia and hypocalcemia.

Technology:

IMMULITE Intact PTH is a solid-phase, two-site chemiluminescent immunometric assay. The solid phase, a polystyrene bead enclosed within an IMMULITE Test Unit, is coated with an affinity-purified murine monoclonal anti-PTH (44-84) anitbody.

The patient sample and alkaline phosphatase-conjugated affinity purified goat polyclonal anti-PTH (1-34) antibody are incubated for approximately 60 minutes at 37°C in the Test Unit with intermittent agitation, intact PTH in the sample is bound to form an antibody sandwich complex. Unbound 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 intact PTH in the sample.

IMMULITE 2000 Intact PTH is a solid-phase, two-site chemiluminescent immunometric assay. The solid phase is a polystyrene bead coated with an affinity-purified murine monoclonal anti-PTH (44-84) anitbody.

The patient sample and alkaline phosphatase-conjugated affinity-purified goat polyclonal anti-PTH (1-34) antibody are introduced into the Reaction Tube containing the bead and incubated for approximately 60 minutes at 37°C with intermittent agitation. During this time, intact PTH in the sample is bound to form an antibody sandwich complex. Unbound conjugate is then removed

Technology (continued):
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 intact PTH in the sample.

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 Intact PTH and IMMULITE 2000 Intact PTH.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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

NOV 2 0 2001

Re: k013566
Trade/Device Name: IMMULITE® Intact PTH and IMMULITE® 2000 intact PTH
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Code: CEW
Dated: October 25, 2001
Received: October 26, 2001

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K013566

NOV 2 0 2001

Device Name: IMMULITE® Intact PTH
IMMULITE® 2000 Intact PTH

Indications For Use: The IMMULITE® Intact PTH and IMMULITE® 2000 Intact PTH assays are for *in vitro* diagnostic use with their respective analyzers for the quantitative measurement of intact parathyroid hormone (parathyrin, PTH) in EDTA plasma or serum, as an aid in the differential diagnosis of hypercalcemia and hypocalcemia.

Thomas C. Donovan

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013566

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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)

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

(Optional Format 1-2-96)