

K994085

JAN 28 2000

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: Diagnostic Products Corporation
Address: 5700 West 96th Street
Los Angeles, California 90045-5597

Telephone Number: (310) 645-8200
Facsimile Number: (310) 645-9999

Contact Person: Edward M. Levine, Ph.D.
Director of Clinical Affairs

Date of Preparation: December 1, 1999

Device Name:
Trade: IMMULITE[®] Turbo HCG
Catalog Number: LSKCG1 (100 tests), LSKCG5 (500 tests)
Common: Reagent system for the determination of human chorionic gonadotropin in serum or plasma.

Classification: Class II device, DHA (21 CFR 862.1155)

Panel: Clinical Chemistry

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:** DPC's IMMULITE[®] HCG

Description of Device: IMMULITE[®] Turbo HCG is a two-site chemiluminescent enzyme immunometric assay for use with the IMMULITE[®] Automated Analyzer.

**Intended Use of the
Device:** IMMULITE[®] Turbo HCG is a solid-phase, two-site

chemiluminescent enzyme immunometric assay for use with the IMMULITE[®] Automated Analyzer and designed for the quantitative measurement of HCG in serum or plasma. It is intended strictly for *in vitro* use as an aid in the detection of pregnancy.

Technology Comparison:

Provided for the reviewer is an explanation of DPC's IMMULITE *Turbo* HCG and IMMULITE HCG Kit 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 *Turbo* assay submissions.

IMMULITE *Turbo* HCG is a solid-phase, two-site chemiluminescent immunometric assay. The solid phase, a polystyrene bead enclosed within an IMMULITE Test Unit, coated with a monoclonal antibody specific for HCG beta subunit. While the patient sample and alkaline phosphatase-conjugated polyclonal antibody are incubated for approximately 6 minutes at 37°C In the Test Unit with intermittent agitation, HCG 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 4 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 HCG in the sample.

IMMULITE HCG is a solid-phase, two-site chemiluminescent immunometric assay. The solid phase, a polystyrene bead enclosed within an IMMULITE Test Unit, coated with a monoclonal antibody specific for HCG beta subunit. While the patient sample and alkaline phosphatase-conjugated polyclonal antibody are incubated for approximately 30 minutes at 37°C In the Test Unit with intermittent agitation, HCG 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 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 HCG in the sample.

Performance Equivalence:

Diagnostic Products Corporation asserts that IMMULITE *Turbo* HCG assay produces substantially equivalent results to other commercially marketed HCG assays, such as the IMMULITE HCG Kit. Each product is designed for the quantitative measurement of HCG. Each product is intended strictly for *in vitro* diagnostic use as an aid in the detection of pregnancy.

Method Comparison:

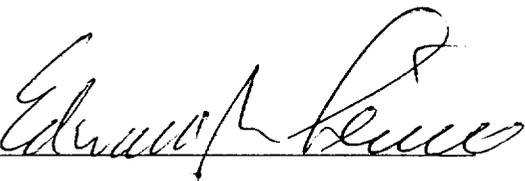
The IMMULITE *Turbo* HCG procedure was compared to DPC's IMMULITE HCG on 60 patient serum samples, with HCG concentrations ranging from approximately 8 mIU/mL to over 3,000 mIU/mL. Linear regression analysis yielded the following statistics:

$$(IMMULITE\ Turbo) = 1.0 (IMMULITE) - 12\ mIU/mL \qquad r = 0.999$$

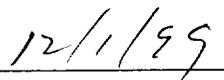
Means: 439 mIU/mL (IMMULITE *Turbo*)
 445 mIU/mL (IMMULITE)

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® *Turbo* HCG.



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



Date



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 28 2000

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

Re: K994085
Trade Name: IMMULITE® Turbo HCG
Regulatory Class: II
Product Code: DHA
Dated: December 1, 1999
Received: December 3, 1999

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 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.

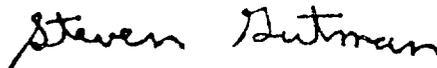
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (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.

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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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

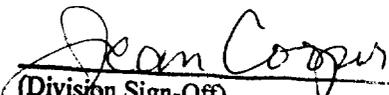
Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K 994085
Device Name: IMMULITE® Turbo HCG

Indications For Use:

IMMULITE *Turbo* HCG is a solid-phase, two-site chemiluminescent enzyme immunometric assay for use with the IMMULITE Automated Analyzer and designed for the quantitative measurement of human chorionic gonadotropin (HCG) in serum, and Heparinized or EDTA plasma. It is intended strictly for *in vitro* use as an aid in the detection of pregnancy.


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K994085

(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-