OCT 1 0 2003

K032881

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:	September 9, 2003
Device Name:	
Trade:	IMMULITE®/IMMULITE® 1000 Total Testosterone IMMULITE® 2000 Total Testosterone
Catalog Number:	LKTW1 (100 tests), LKTW5 (500 tests) L2KTW2 (200 tests), L2KTW6 (600 tests)
CFR:	A testosterone test system is a device intended to measure testosterone (a male sex hormone) in serum, plasma, and urine. Measurements of testosterone are used in the diagnosis and treatment of disorders involving the male sex hormones (androgens), including primary and secondary hypogonadism, delayed or precocious puberty, impotence in males and, in females hirsutism (excessive hair) and virilization (masculinization) due to tumors, polycystic ovaries, and adrenogenital syndromes.
Common:	Reagent system for the determination of testosterone in serum and plasma.
Classification:	Class I device, CDZ (21CFR 862.1680)
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/IMMULITE 1000 Total Testosterone (K022603)
IMMULITE 2000 Total Testosterone (K955870)

Description of Device:

IMMULITE/IMMULITE 1000 Total Testosterone is a solid-phase, two-site competitive chemiluminescent immunoassay for use with the IMMULITE and IMMULITE 1000 Analyzers.

IMMULITE 2000 Total Testosterone is a solid-phase, two-site competitive chemiluminescent immunoassay for use with the IMMULITE 2000 Analyzer.

Intended Use of the Device:

IMMULITE/IMMULITE 1000 Total Testosterone: For *in vitro* diagnostic use with the IMMULITE and IMMULITE 1000 Analyzers — for the quantitative measurement of testosterone in serum and plasma, as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen.

IMMULITE 2000 Total Testosterone: For *in vitro* diagnostic use with the IMMULITE 2000 Analyzer — for the quantitative measurement of total testosterone in serum and plasma, as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen.

Technology:

IMMULITE/IMMULITE 1000 Total Testosterone is a solid-phase, enzyme-labeled, competitive chemiluminescent immunoassay. The solid-phase, a polystyrene bead enclosed within an IMMULITE Test Unit, is coated with a polyclonal rabbit antibody specific for testosterone.

The patient sample and alkaline phosphatase-labeled testosterone are simultaneously introduced into the Test Unit, and incubated for approximately 60 minutes at 37°C with intermittent agitation. During this time, testosterone in the sample competes with alkaline phosphatase-labeled testosterone for antibody-binding sites on the bead. Unbound material is then removed by a centrifugal wash. Substrate is then 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 inversely proportional to the concentration of testosterone in the sample.

IMMULITE 2000 Total Testosterone is a solid-phase, enzyme-labeled, competitive chemiluminescent immunoassay. The solid-phase, a polystyrene bead is coated with a polyclonal rabbit antibody specific for testosterone.

The patient sample and alkaline phosphatase-labeled testosterone are simultaneously introduced into the Reaction Tube, containing the coated bead, and incubated for approximately 60 minutes at 37°C with intermittent agitation. During this time, testosterone in the sample competes with alkaline phosphatase-labeled testosterone for antibody-binding sites on the bead. Unbound material is then removed by a centrifugal wash. Substrate is then 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 inversely proportional to the concentration of testosterone 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/IMMULITE 1000 Total Testosterone and IMMULITE 2000 Total Testosterone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 1 0 2003

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

Re: k032881
Trade/Device Name: IMMULITE®/IMMULITE® 1000 Total Testosterone
IMMULITE® 2000 Total Testosterone
Regulation Number: 21 CFR 862.1680
Regulation Name: Testosterone test system
Regulatory Class: Class I
Product Code: CDZ
Dated: September 9, 2003
Received: September 22, 2003

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). You may obtain other general information on your responsibilities under the Act 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):
Device Name: IMMULITE®/IMMULITE® 1000 Total Testosterone
IMMULITE® 2000 Total Testosterone

Indications For Use:

The IMMULITE/IMMULITE 1000 Total Testosterone is for *in vitro* diagnostic use with the IMMULITE and IMMULITE 1000 Analyzers — for the quantitative measurement of testosterone in serum and plasma, as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen.

The IMMULITE 2000 Total Testosterone is for *in vitro* diagnostic use with the IMMULITE 2000 Analyzer — for the quantitative measurement of total testosterone in serum and plasma, as an aid in the diagnosis and management of conditions involving excess or deficiency of this androgen.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

✓
Prescription Use (Per 21 CFR 801.109) **510(k)** K032881 OR Over-The-Counter Use

(Optional Format 1-2-96)