K012311

AUG 2 0 2001

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:	July 20, 2001
Device Name: Trade:	IMMULITE® 2000 Gentamicin
Catalog Number:	L2KGE2 (200 tests), L2KGE6 (600 tests)
CFR:	A gentamicin test system is a device intended to measure gentamicin, an antibiotic drug, in human specimens. Measurements obtained by this device are used in the diagnosis and treatment of gentamicin overdose and in monitoring levels of gentamicin to ensure appropriate therapy.
Common:	Reagent system for the determination of gentamicin in plasma and serum.
Classification:	Class II device, LCD (21 CFR 862.3450)
Panel:	Toxicology
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:	Abbott AxSYM® Gentamicin (K935376)
Description of Device:	IMMULITE® 2000 Gentamicin is a solid-phase, chemiluminescent enzyme immunoassay for use with the IMMULITE® 2000 Automated Analyzer.
Intended Use of the Device:	IMMULITE® 2000 Gentamicin is for *in vitro* diagnostic use with the IMMULITE 2000 Analyzer - for the quantitative measurement of gentamicin in serum or plasma, as an aid in monitoring the therapeutic administration of this aminoglycoside.

Technology:

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

IMMULITE 2000 Gentamicin is a solid-phase, chemiluminescent competitive immunoassay. The solid-phase, a polystyrene bead, is coated with a polyclonal rabbit antibody specific for gentamicin.

The patient sample and a buffer matrix are introduced into the sample pretreatment cup and incubated for 30 minutes at 37°C. The diluted sample is then transferred with alkaline phosphatase-labeled gentamicin into the Reaction Tube containing a gentamicin antibody-coated bead and incubated for another 30-minutes cycle at 37°C with intermittent agitation. During this time, gentamicin in the samples competes with enzyme-labeled gentamicin for a limited number of antibody binding sites on the bead. Unbound enzyme conjugate is then removed by a centrifugal wash, after which substrate is added and the Reaction Tube is incubated for an additional 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 gentamicin in the sample.

Abbott AxSYM Gentamicin utilizes fluorescence polarization immunoassay technology in a competitive ligand format. The unlabeled antibiotic (antigen being measured) competes with the fluorescent-labeled antigen for the antibody binding sites. With increasing concentration of unlabeled antigen, more fluorescent-labeled antigen becomes unbound. Therefore, the fluorescent polarization signal decreases as the drug concentration increases, as measured by the fluorometer. Concentrations are determined from a stored standard curve.

Performance Equivalence:

Diagnostic Products Corporation asserts that the IMMULITE® 2000 Gentamicin produces substantially equivalent results to other commercially marketed gentamicin assays, such as Abbott AxSYM® Gentamicin. The assay, Abbott AxSYM® Gentamicin utilizes fluorescence polarization technology. Each product is designed for the quantitative measurement of gentamicin in serum or plasma. Each product is intended strictly for in vitro diagnostic use as an aid in monitoring the therapeutic administration of this drug.

Method Comparison:

The IMMULITE 2000 Gentamicin procedure was compared to a commercially available gentamicin assay (Abbott AxSYM® Gentamicin) on 89 patient samples, with gentamicin concentrations ranging from approximately 0.5 to 8.0 µg/mL. Linear regression analysis yielded the following statistics.

(IMMULITE 2000) = 0.94 (Abbott AxSYM® Gentamicin) + 0.2 µg/mL

r = 0.973

Means: 3.0 µg/mL (IMMULITE 2000)
2.9 µg/mL (Abbott AxSYM®)

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® 2000 Gentamicin.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 0 2001

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

Re: 510(k) Number: K012311
Trade/Device Name: IMMULITE®2000 Gentamicin
Regulation Number: 862.3450
Regulatory Class: II
Product Code: LCD
Dated: July 20, 2001
Received: July 23, 2001

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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): K012311

Device Name: IMMULITE®2000 Gentamicin

Indications For Use:

For *in vitro* diagnostic use with the IMMULITE 2000 Analyzer – for the quantitative measurement of gentamicin in serum or plasma, as an aid in monitoring the therapeutic administration of this aminoglycoside.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kesia Alexander for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012311

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

(Optional Format 1-2-96)