

AUG 20 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: Diagnostic Products Corporation
Address: 5700 West 96th Street
Los Angeles, CA 90045

Telephone Number: (310) 645-8200
Facsimile Number: (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 Tobramycin
Catalog Number: L2KTC2 (200 tests), L2KTC6 (600 tests)

CFR: A tobramycin test system is a device intended to measure tobramycin, an aminoglycoside antibiotic drug, in plasma and serum. Measurements obtained by this device are used in the diagnosis and treatment of tobramycin overdose and in monitoring levels of tobramycin to ensure appropriate therapy.

Common: Reagent system for the determination of tobramycin in plasma and serum.

Classification: Class II device, KLB (21 CFR 862.3900)

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® Tobramycin (K941614)

Description of Device: IMMULITE® 2000 Tobramycin is a solid-phase, chemiluminescent enzyme immunoassay for use with the IMMULITE® 2000 Automated Analyzer.

**Intended Use of the
Device:** IMMULITE® 2000 Tobramycin is for *in vitro* diagnostic use with the IMMULITE® 2000 Analyzer - for the quantitative measurement of tobramycin 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 Tobramycin is a solid-phase, chemiluminescent competitive immunoassay. The solid-phase, a polystyrene bead, is coated with a polyclonal rabbit antibody specific for tobramycin.

The patient sample and alkaline phosphatase-labeled tobramycin are simultaneously introduced into the Reaction Tube and incubated for approximately 30 minutes at 37 °C with intermittent agitation. During this time, tobramycin in the samples competes with enzyme-labeled tobramycin 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 tobramycin in the sample.

Abbott AxSYM® Tobramycin 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 Tobramycin produces substantially equivalent results to other commercially marketed Tobramycin assays, such as Abbott AxSYM® Tobramycin. The assay, Abbott AxSYM® Tobramycin utilizes fluorescence polarization technology. Each product is designed for the quantitative measurement of tobramycin 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 Tobramycin procedure was compared to a commercially available assay (Abbott AxSYM® Tobramycin) on 41 patient samples, with tobramycin concentrations ranging from approximately 1.1 to 11.0 µg/mL. Linear regression analysis yielded the following statistics.

$$(\text{IMMULITE 2000}) = 0.96 (\text{Abbott AxSYM}^{\circledR} \text{Tobramycin}) - 0.18 \mu\text{g/mL}$$

$$r = 0.981$$

Means: 3.76 µg/mL (IMMULITE 2000)
 4.10 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 Tobramycin.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 20 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: K012312
Trade/Device Name: IMMULITE®2000 Tobramycin
Regulation Number: 862.3900
Regulatory Class: II
Product Code: KLB
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.

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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 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large, prominent "S" at the beginning.

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

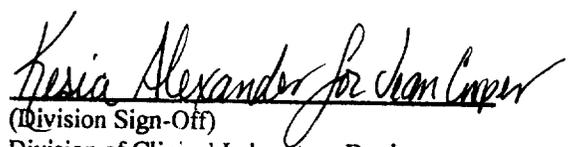
510(k) Number (if known): K012312
Device Name: IMMULITE®2000 Tobramycin

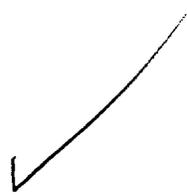
Indications For Use:

For *in vitro* diagnostic use with the IMMULITE 2000 Analyzer – for the quantitative measurement of tobramycin 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)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012312



Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use