

K983391

OUT 15 1998

**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:** September 23, 1998

**Catalog Number:** L2KOP2

**Device Name**  
**Trade:** IMMULITE® 2000 OM-MA

**Common:** Reagent system for the measurement of CA 125 antigen in human serum.

**Classification:** LTK, class II device

**Manufacturer:** Euro/DPC Limited  
Glyn Rhonwy  
Lanberis, Gwynedd LL55 4EL  
United Kingdom  
(Manufactured under a Quality System-  
ISO 9001/EN29001/BS 5750)

**Sole U. S. Importer:** Diagnostic Products Corporation  
5700 West 96<sup>th</sup> Street  
Los Angeles, CA 90045-5597

**Establishment**  
**Registration #:** Euro/DPC – Not applicable  
DPC Registration number is 2017183

**Substantially Equivalent**  
**Predicate Device:** IMMULITE® OM-MA (K981297)

**Description of Device:**

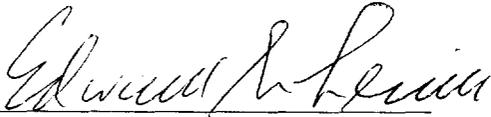
IMMULITE<sup>®</sup> 2000 OM-MA is a clinical use device intended for use with the IMMULITE<sup>®</sup> 2000 Automated Immunoassay Analyzer

**Intended Use of the Device:**

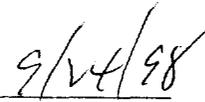
IMMULITE<sup>®</sup> 2000 OM-MA is a solid-phase, chemiluminescent enzyme immunometric assay for use with the IMMULITE<sup>®</sup> 2000 Automated Analyzer and designed for the quantitative measurement of CA 125 antigen in serum. It is intended strictly for *in vitro* diagnostic use as an aid in monitoring the response to therapy for patients with epithelial ovarian cancer, and in detecting residual ovarian cancer in patients who have undergone first-line therapy and would be considered for diagnostic second-look procedures.

**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<sup>®</sup> OM-MA.



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



Date



OCT 15 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Edward M. Levine, Ph.D.  
Director of Clinical Affairs  
Diagnostic Products Corporation  
5700 West 96<sup>th</sup> Street  
Los Angeles, California 90045

Re: K983391  
Trade Name: IMMULITE® 2000 OM-MA and IMMULITE® OM-MA Control  
Module Catalog # L2KOP2 (200 Tests) LOMCM (Control Module)  
Regulatory Class: II  
Product Code: LTK  
Dated: September 23, 1998  
Received: September 25, 1998

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.

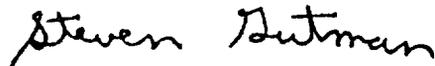
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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" (21 CFR 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 cursive script that reads "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

