

MAY - 9 1997

**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: (213) 776-0180
Facsimile Number: (213) 776-0204
Contact Person: Edward M. Levine, Ph.D.
Director of Clinical Affairs
Date of Preparation: March 20, 1997
Device Name: WinMAX software system
Trade: Software program for processing AlaSTAT and AlaTOP immunodiagnostic allergy test kits.
Catalog Number: WinMAX
Classification: Class I device, (21 CFR 862.2300)
Level of Concern: We believe the level of concern of this device to be minor, based on definitions established in the "Review Guidance for Computer Controlled Medical Devices Undergoing 510(k) Review"
Hazards associated with the device: We believe the hazards associated with malfunction of the device to be minimal. At the worst, software malfunction could lead to misdiagnosis of patient allergy.
Manufacturer: EURO/DPC Ltd., a wholly-owned subsidiary of DPC (Manufacturing under a Quality System-ISO 9002/EN29002/BS 5750)
Sole U.S. Importer: Diagnostic Products Corporation (DPC)
5700 West 96th Street
Los Angeles, CA 90045-5597
Establishment Registration Number: DPC's Registration Number is 2017183
Description of Device: Software program
Intended Use of the Device: DPC's WinMAX software system is a comprehensive software program for processing DPC's in vitro diagnostic assays, the AlaSTAT and AlaTOP immunodiagnostic allergy test kits, in the microtiter plate format. It is intended for in vitro diagnostic use only.

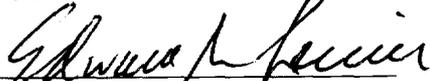
Diagnostic Products Corporation
WinMAX Software System
April 10, 1997

Method Comparison:

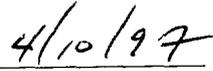
To demonstrate the equivalence of the performance of the WinMAX and MAXsoftware systems, a comparison was made of 262 serum samples tested for a variety of allergens using both software systems. Of the 262 samples tested, 163 samples gave quantitative results that were within the reportable ranges of both software systems. Linear regression of these 163 sample results yielded: $\text{WinMAX} = 0.76 * \text{MAXsoftware} + 0.91 \text{ KU/L}$, with a correlation coefficient of 0.960.

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the device is safe and effective.



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



Date