

**K981297 IMMULITE OM-MA, MODELS LKOPZ, LKOP1, LKOP5**Sep 18, 1998  
163 days to decisionK981297 · Product code: **LTK** · Immunology  
Source: <https://www.510kdatabase.net/k981297/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Apr 8, 1998
Decision date	Sep 18, 1998
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Diagnostic Products Corp.</b>
Location	Mchenry, IL, US
Contact	EDWARD M LEVINE
510(k) history	321 submissions · 321 cleared · 1976-2006

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k981297/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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