

**K983391 IMMULITE 2000 OM-MA MODEL L2KOP2**Oct 15, 1998  
20 days to decisionK983391 · Product code: LTK · Immunology  
Source: <https://www.510kdatabase.net/k983391/>**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	Sep 25, 1998
Decision date	Oct 15, 1998
Days to decision	20 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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