

**K972095 IMMULITE 2000 PSA**Aug 22, 1997  
79 days to decisionK972095 · Product code: **LTJ** · Immunology  
Source: <https://www.510kdatabase.net/k972095/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prostate-specific Antigen (psa) For Management Of Prostate Cancers (LTJ)
Date received	Jun 4, 1997
Decision date	Aug 22, 1997
Days to decision	79 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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

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