

**K980716 ADVANTAGE CHEMILUMINESCENCE PROSTATE SPECIFIC ANTIGEN (PSA) IMMUNOASSAY**Apr 3, 1998  
86 days to decisionK980716 · Product code: **LTJ** · Immunology  
Source: <https://www.510kdatabase.net/k980716/>**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	Jan 7, 1998
Decision date	Apr 3, 1998
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nichols Institute Diagnostics</b>
Location	Mchenry, IL, US
Contact	DAVE SMITH
510(k) history	68 submissions · 68 cleared · 1977-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k980716/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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