

**K011068 RHIGENE NDNA TEST SYSTEM FOR IMAGETITER,  
MODEL CL100L**Apr 11, 2002  
367 days to decisionK011068 · Product code: **KTL** · Immunology  
Source: <https://www.510kdatabase.net/k011068/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-dna Indirect Immunofluorescent Solid Phase (KTL)
Date received	Apr 9, 2001
Decision date	Apr 11, 2002
Days to decision	367 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Rhigene, Inc.</b>
Location	Des Plaines, IL, US
Contact	DAVID KOLESAR
510(k) history	15 submissions · 15 cleared · 2000-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011068/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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