

**K101911 IMMUKNOW-THE CYLEX IMMUNE CELLFUNCTION  
ASSAY**Oct 18, 2010  
101 days to decisionK101911 · Product code: **NID** · Hematology  
Source: <https://www.510kdatabase.net/k101911/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Assay, Proliferation, In Vitro, T Lymphocyte (NID)
Date received	Jul 9, 2010
Decision date	Oct 18, 2010
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Cylex, Inc.</b>
Location	Baldwin, MD, US
Contact	Judi Smith
510(k) history	2 submissions · 2 cleared · 2002-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k101911/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 20, 2026