

**K001647 BN PROSPEC SYSTEM**Sep 26, 2000  
119 days to decisionK001647 · Product code: **JZW** · Immunology  
Source: <https://www.510kdatabase.net/k001647/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nephelometer (JZW)
Date received	May 30, 2000
Decision date	Sep 26, 2000
Days to decision	119 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dade Behring, Inc.</b>
Location	Newark,, DE, US
Contact	REBECCA S AYASH
510(k) history	343 submissions · 343 cleared · 1978-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k001647/> 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 19, 2026