

**K092399 ANTI-MUTATED CITRULLINATED VIMENTIN EIA**Jul 1, 2010  
329 days to decisionK092399 · Product code: **OQZ** · Immunology  
Source: <https://www.510kdatabase.net/k092399/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Anti-mutated Citrullinated Vimentin Igg (OQZ)
Date received	Aug 6, 2009
Decision date	Jul 1, 2010
Days to decision	329 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Orgentec Diagnostika GmbH</b>
Location	Minneapolis, MN, US
Contact	Gary Lehnus
510(k) history	3 submissions · 3 cleared · 2003-2010

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k092399/> 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