

**K100499 ORGENTEC RHEUMATOID FACTOR EIA**Oct 27, 2010  
247 days to decisionK100499 · Product code: **DHR** · Immunology  
Source: <https://www.510kdatabase.net/k100499/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Rheumatoid Factor (DHR)
Date received	Feb 22, 2010
Decision date	Oct 27, 2010
Days to decision	247 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/k100499/> 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