

**K081709 OLYMPUS AFP - ALPHA-FETOPROTEIN**Mar 16, 2009  
272 days to decisionK081709 · Product code: **LOJ** · Immunology  
Source: <https://www.510kdatabase.net/k081709/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test,alpha-fetoprotein For Testicular Cancer (LOJ)
Date received	Jun 17, 2008
Decision date	Mar 16, 2009
Days to decision	272 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Olympus Life Science Research Europa GmbH (Europa)</b>
Location	Irving, TX, US
Contact	STEPHANIE G DONNELLY
510(k) history	3 submissions · 3 cleared · 2008-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081709/> 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 23, 2026