

**K080094 OLYMPUS TOTAL BHCG TEST SYSTEM**Sep 3, 2008  
233 days to decisionK080094 · Product code: **DHA** · Chemistry  
Source: <https://www.510kdatabase.net/k080094/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Human Chorionic Gonadotropin (DHA)
Date received	Jan 14, 2008
Decision date	Sep 3, 2008
Days to decision	233 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 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/k080094/> 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