

**K911047 OBA(TM) SERUM HCG ASSAY**Jun 24, 1991  
108 days to decisionK911047 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k911047/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Mar 8, 1991
Decision date	Jun 24, 1991
Days to decision	108 days
Third-party review	No

**APPLICANT**

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Company	<b>Adeza Biomedical</b>
Location	Sunnyvale, CA, US
Contact	YUH-GENG TSAY
510(k) history	3 submissions · 3 cleared · 1990-1991

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911047/>; 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 30, 2026