

**K911217 SR1 T4 ENZYME IMMUNOASSAY (MAGNETIC SOLID-PHASE)**Aug 16, 1991  
150 days to decisionK911217 · Product code: **KLI** · Chemistry  
Source: <https://www.510kdatabase.net/k911217/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	Mar 19, 1991
Decision date	Aug 16, 1991
Days to decision	150 days
Third-party review	No

**APPLICANT**

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Company	<b>Serono-Baker Diagnostics, Inc.</b>
Location	Winchester, VA, US
Contact	DAVID THOMAS
510(k) history	23 submissions · 23 cleared · 1988-1992

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k911217/>; 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 29, 2026