

**K897193 OPUS T4 TEST SYSTEM**Mar 19, 1990  
80 days to decisionK897193 · Product code: **KLI** · Toxicology  
Source: <https://www.510kdatabase.net/k897193/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	Dec 29, 1989
Decision date	Mar 19, 1990
Days to decision	80 days
Third-party review	No

**APPLICANT**

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Company	<b>Pb Diagnostic Systems, Inc.</b>
Location	Westwood, MA, US
Contact	LORI BARANAUSKAS
510(k) history	35 submissions · 35 cleared · 1988-1994

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k897193/>; 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