

**K944703 THYROXINE ENZYME IMMUNOASSAY**Dec 9, 1994  
77 days to decisionK944703 · Product code: **KLI** · Chemistry  
Source: <https://www.510kdatabase.net/k944703/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	Sep 23, 1994
Decision date	Dec 9, 1994
Days to decision	77 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Diagnostic Reagents, Inc.</b>
Location	Walker, MI, US
Contact	YUH-GENG TSAY
510(k) history	66 submissions · 66 cleared · 1982-1998

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k944703/> 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 28, 2026