

**K864231 U.S. DIAGNOSTICS ENZYMATIC TRIGLYCERIDE TEST**Dec 4, 1986  
37 days to decisionK864231 · Product code: **CDT** · Chemistry  
Source: <https://www.510kdatabase.net/k864231/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipase Hydrolysis/glycerol Kinase Enzyme, Triglycerides (CDT)
Date received	Oct 28, 1986
Decision date	Dec 4, 1986
Days to decision	37 days
Third-party review	No

**APPLICANT**

---

Company	<b>U. S. Diagnostics, Inc.</b>
Location	San Luis Obispo, CA, US
Contact	ROY E SPECK
510(k) history	22 submissions · 22 cleared · 1986-2011

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864231/>, 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 18, 2026