

**K932980 TOTAL T4 FPIA REAGENT SET/CALIBRATOR  
#T-1039,T-116**Oct 18, 1993  
123 days to decisionK932980 · Product code: **CDX** · Chemistry  
Source: <https://www.510kdatabase.net/k932980/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Thyroxine (CDX)
Date received	Jun 17, 1993
Decision date	Oct 18, 1993
Days to decision	123 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Sigma Diagnostics, Inc.</b>
Location	Mchenry, IL, US
Contact	BARRY ROBINS
510(k) history	164 submissions · 164 cleared · 1984-2002

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k932980/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026