

**K952557 TOTAL T-3 FPIA REAGENT SET, TOTAL T-3 FPIA CALIBRATORS**Jan 24, 1996  
236 days to decisionK952557 · Product code: **CDP** · Chemistry  
Source: <https://www.510kdatabase.net/k952557/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Total Triiodothyronine (CDP)
Date received	Jun 2, 1995
Decision date	Jan 24, 1996
Days to decision	236 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k952557/> 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