

**K955097 AMERLITE MAB FT4 ASSAY**Dec 20, 1995  
43 days to decisionK955097 · Product code: **CEC** · Chemistry  
Source: <https://www.510kdatabase.net/k955097/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Free Thyroxine (CEC)
Date received	Nov 7, 1995
Decision date	Dec 20, 1995
Days to decision	43 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Kodak Clinical Diagnostics, Ltd.</b>
Location	Buckinghamshire, GB
Contact	SARAH CLARK
510(k) history	1 submissions · 1 cleared · 1995-1995

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k955097/> 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 July 1, 2026