

**K854183 IN VITRO TEST DETERMINATION OF THEOPHYLLINE**Dec 19, 1985  
65 days to decisionK854183 · Product code: **KLS** · Toxicology  
Source: <https://www.510kdatabase.net/k854183/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Theophylline (KLS)
Date received	Oct 15, 1985
Decision date	Dec 19, 1985
Days to decision	65 days
Third-party review	No

**APPLICANT**

---

Company	<b>Clinical Data, Inc.</b>
Location	Mchenry, IL, US
Contact	ISRAEL M STEIN
510(k) history	36 submissions · 36 cleared · 1982-2007

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k854183/>; 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 May 27, 2026