

**K800301 SIGMA PROCEDURE & REAGENT SYSTEM #335-UV**Mar 5, 1980  
23 days to decisionK800301 · Product code: **CDT** · Chemistry  
Source: <https://www.510kdatabase.net/k800301/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lipase Hydrolysis/glycerol Kinase Enzyme, Triglycerides (CDT)
Date received	Feb 11, 1980
Decision date	Mar 5, 1980
Days to decision	23 days
Third-party review	No

**APPLICANT**

---

Company	<b>Sigma Chemical Co.</b>
Location	Mchenry, IL, US
Website	<a href="https://www.sigmaaldrich.com">https://www.sigmaaldrich.com</a>
510(k) history	231 submissions · 231 cleared · 1976-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k800301/>, 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 14, 2026