

**K780466 EMIT CARBAMAZEPINE ASSAY**Apr 24, 1978  
33 days to decisionK780466 · Product code: **KLT** · Toxicology  
Source: <https://www.510kdatabase.net/k780466/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Carbamazepine (KLT)
Date received	Mar 22, 1978
Decision date	Apr 24, 1978
Days to decision	33 days
Third-party review	No
Combination product	No
PCCP authorized	No

**APPLICANT**

---

Company	<b>Syva Co.</b>
Location	Mchenry, IL, US
510(k) history	448 submissions · 447 cleared · 1976-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k780466/> 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 June 28, 2026