

**K853372 GEMSTAR IPA THEOPHYLLINE TEST KIT**Sep 4, 1985  
23 days to decisionK853372 · Product code: **KLS** · Toxicology  
Source: <https://www.510kdatabase.net/k853372/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Theophylline (KLS)
Date received	Aug 12, 1985
Decision date	Sep 4, 1985
Days to decision	23 days
Third-party review	No

**APPLICANT**

---

Company	<b>Electro-Nucleonics Laboratories, Inc.</b>
Location	Mchenry, IL, US
Contact	EUGENE H LABREC
510(k) history	41 submissions · 41 cleared · 1976-1988

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k853372/>, 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 29, 2026