

**K934125 GONOCHEK-II, MODIFICATION**Sep 9, 1994  
393 days to decisionK934125 · Product code: **JTO** · Microbiology  
Source: <https://www.510kdatabase.net/k934125/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Discs, Strips And Reagents, Microorganism Differentiation (JTO)
Date received	Aug 12, 1993
Decision date	Sep 9, 1994
Days to decision	393 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>E-Y Laboratories, Inc.</b>
Location	Mchenry, IL, US
Contact	LINDA M WERTZ
510(k) history	13 submissions · 13 cleared · 1983-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k934125/> 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 30, 2026