

**K864607 EASY-TEST QUINIDINE ITEM NO. 67---/95**Jan 8, 1987  
45 days to decisionK864607 · Product code: **LBZ** · Toxicology  
Source: <https://www.510kdatabase.net/k864607/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Quinidine (LBZ)
Date received	Nov 24, 1986
Decision date	Jan 8, 1987
Days to decision	45 days
Third-party review	No

**APPLICANT**

---

Company	<b>Em Diagnostic Systems, Inc.</b>
Location	Walker, MI, US
Contact	RAYMOND L MILLER
510(k) history	288 submissions · 288 cleared · 1984-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k864607/>; 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