

**K923959 ALBUMIN TEST**Dec 28, 1992  
144 days to decisionK923959 · Product code: **CIX** · Chemistry  
Source: <https://www.510kdatabase.net/k923959/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bromocresol Green Dye-binding, Albumin (CIX)
Date received	Aug 6, 1992
Decision date	Dec 28, 1992
Days to decision	144 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k923959/> 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