

K932159 SYSTEMATE DIRECT BILIRUBIN CAT. NO. 65406Sep 21, 1993
140 days to decisionK932159 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k932159/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	May 4, 1993
Decision date	Sep 21, 1993
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k932159/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026