

K923083 TOTAL BILIRUBIN CATALOG NO. 65407Sep 9, 1992
76 days to decisionK923083 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k923083/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Jun 25, 1992
Decision date	Sep 9, 1992
Days to decision	76 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

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