

K895118 SYSTEMATE TOTAL BILIRUBIN CATALOG NO. 65407Oct 17, 1989
63 days to decisionK895118 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k895118/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Aug 15, 1989
Decision date	Oct 17, 1989
Days to decision	63 days
Third-party review	No

APPLICANT

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

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