

K843328 SYSTEMATE T-BILI 67212Sep 20, 1984
24 days to decisionK843328 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k843328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Aug 27, 1984
Decision date	Sep 20, 1984
Days to decision	24 days
Third-party review	No

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k843328/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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