

K983304 SYNERMED NEAR-INFRARED DIRECT BILIRUBIN REAGENT KITNov 4, 1998
44 days to decisionK983304 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k983304/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Sep 21, 1998
Decision date	Nov 4, 1998
Days to decision	44 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Synermed Intl., Inc.
Location	Lachine, Quebec, CA
Contact	MARCIA J ARENTZ
510(k) history	2 submissions · 2 cleared · 1998-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983304/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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