

**K973109 SYNERMED NEAR-INFRARED DIRECT BILIRUBIN REAGENT KIT**Sep 25, 1997  
37 days to decisionK973109 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k973109/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Aug 19, 1997
Decision date	Sep 25, 1997
Days to decision	37 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Synermed, Inc.</b>
Location	Quebec, Canada, CA
Contact	MARCIA J ARENTZ
510(k) history	45 submissions · 45 cleared · 1990-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973109/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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