

**K940570 SYNERMED TOTAL BILIRUBIN REAGENT KIT**Apr 20, 1994  
71 days to decisionK940570 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k940570/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Diazo Colorimetry, Bilirubin (CIG) |
| Date received         | Feb 8, 1994                        |
| Decision date         | Apr 20, 1994                       |
| Days to decision      | 71 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/k940570/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated July 1, 2026