

**K841572 DIRECT BILIRUBIN REAGENT**May 16, 1984  
29 days to decisionK841572 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k841572/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Diazo Colorimetry, Bilirubin (CIG) |
| Date received         | Apr 17, 1984                       |
| Decision date         | May 16, 1984                       |
| Days to decision      | 29 days                            |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Hi Chem, Inc.</b>                    |
| Location       | Mchenry, IL, US                         |
| 510(k) history | 52 submissions · 52 cleared · 1977-1996 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k841572/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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