

**K780524 ULTRACHEM T-BILI 64971 GILFORD 3500**May 19, 1978  
49 days to decisionK780524 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k780524/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Diazo Colorimetry, Bilirubin (CIG) |
| Date received         | Mar 31, 1978                       |
| Decision date         | May 19, 1978                       |
| Days to decision      | 49 days                            |
| Third-party review    | No                                 |

**APPLICANT**

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| Company        | <b>Harleco</b>                            |
| Location       | Mchenry, IL, US                           |
| 510(k) history | 116 submissions · 116 cleared · 1976-1982 |

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

Device record: <https://www.510kdatabase.net/k780524/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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