

K843027 BILIRUBIN ASSAY KIT DIRECTSep 4, 1984
34 days to decisionK843027 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k843027/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Diazo Colorimetry, Bilirubin (CIG) |
| Date received | Aug 1, 1984 |
| Decision date | Sep 4, 1984 |
| Days to decision | 34 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Diagnostic Chemicals, Ltd. (Usa) |
| Location | Walker, MI, US |
| 510(k) history | 77 submissions · 76 cleared · 1984-2002 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k843027/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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