

**K861094 BILIRUBIN ASSAY KIT (DIRECT), CATA. NUMBER  
202-02**Apr 21, 1986  
28 days to decisionK861094 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k861094/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Mar 24, 1986
Decision date	Apr 21, 1986
Days to decision	28 days
Third-party review	No

**APPLICANT**

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Company	<b>Diagnostic Chemicals, Ltd. (Usa)</b>
Location	Walker, MI, US
Contact	CALLBECK, R.T.
510(k) history	77 submissions · 76 cleared · 1984-2002

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k861094/>; 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 June 29, 2026