

K840777 DIRECT BILIRUBIN REAGENTApr 5, 1984
57 days to decisionK840777 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k840777/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Feb 8, 1984
Decision date	Apr 5, 1984
Days to decision	57 days
Third-party review	No

APPLICANT

Company	American Dade
Location	Mchenry, IL, US
510(k) history	149 submissions · 149 cleared · 1980-1987

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Device record: <https://www.510kdatabase.net/k840777/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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