

K861671 DIRECT BILIRUBIN PROCEDUREJun 25, 1986
56 days to decisionK861671 · Product code: **CIG** · Chemistry
Source: <https://www.510kdatabase.net/k861671/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Diazo Colorimetry, Bilirubin (CIG) |
| Date received | Apr 30, 1986 |
| Decision date | Jun 25, 1986 |
| Days to decision | 56 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Data Medical Associates, Inc. |
| Location | Mchenry, IL, US |
| Contact | JERRY A GRAHAM |
| 510(k) history | 111 submissions · 111 cleared · 1978-1999 |

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