

**K880397 DIRECT BILIRUBIN PROCEDURE RUN ON A AU5000 INSTRU.**

Mar 15, 1988  
46 days to decision

K880397 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k880397/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Jan 29, 1988
Decision date	Mar 15, 1988
Days to decision	46 days
Third-party review	No

**APPLICANT**

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Company	<b>Data Medical Associates, Inc.</b>
Location	Mchenry, IL, US
Contact	MARJORIE B POTTS
510(k) history	111 submissions · 111 cleared · 1978-1999

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

Device record: <https://www.510kdatabase.net/k880397/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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