

**K892905 DIRECT BILIRUBIN FOR MANUAL OR AUTOMATED APPLI.**Jun 19, 1989  
60 days to decisionK892905 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k892905/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Apr 20, 1989
Decision date	Jun 19, 1989
Days to decision	60 days
Third-party review	No

**APPLICANT**

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Company	<b>Catachem, Inc.</b>
Location	Port Chester, NY, US
Contact	LUIS P LEON
510(k) history	41 submissions · 41 cleared · 1985-2007

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

Device record: <https://www.510kdatabase.net/k892905/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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