

**K030003 ATAC DIRECT BILIRUBIN REAGENT AND CALIBRATOR**Sep 29, 2003  
270 days to decisionK030003 · Product code: **CIG** · Chemistry  
Source: <https://www.510kdatabase.net/k030003/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diazo Colorimetry, Bilirubin (CIG)
Date received	Jan 2, 2003
Decision date	Sep 29, 2003
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Elan Diagnostics</b>
Location	Brea, CA, US
Contact	WYNN STOCKING
510(k) history	13 submissions · 13 cleared · 1999-2003

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k030003/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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