

**K834053 DART ALPHA-AMYLASE REAGENT SYSTEM**Feb 4, 1984  
73 days to decisionK834053 · Product code: **CIJ** · Chemistry  
Source: <https://www.510kdatabase.net/k834053/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Saccharogenic, Amylase (CIJ)
Date received	Nov 23, 1983
Decision date	Feb 4, 1984
Days to decision	73 days
Third-party review	No

**APPLICANT**

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Company	<b>Coulter Electronics, Inc.</b>
Location	Mchenry, IL, US
510(k) history	101 submissions · 101 cleared · 1976-1994

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

Device record: <https://www.510kdatabase.net/k834053/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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