

**K121256 ALCO-SCREEN 02**Sep 12, 2012  
140 days to decisionK121256 · Product code: **DIC** · Toxicology  
Source: <https://www.510kdatabase.net/k121256/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                      |
| Submission type       | Traditional   |
| Device classification | Alcohol Dehydrogenase, Specific Reagent For Ethanol Enzyme Method (DIC) |
| Date received         | Apr 25, 2012  |
| Decision date         | Sep 12, 2012  |
| Days to decision      | 140 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Chematics, Inc.</b>                |
| Location       | North Webster, IN, US                 |
| Contact        | CARL REYNOLDS                         |
| 510(k) history | 2 submissions · 2 cleared · 2012-2013 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k121256/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 9, 2026