

**K850923 BUN (RATE) REAGENT**Mar 20, 1985  
15 days to decisionK850923 · Product code: **CDQ** · Chemistry  
Source: <https://www.510kdatabase.net/k850923/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Urease And Glutamic Dehydrogenase, Urea Nitrogen (CDQ) |
| Date received         | Mar 5, 1985  |
| Decision date         | Mar 20, 1985   |
| Days to decision      | 15 days  |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Sigma Diagnostics, Inc.</b>            |
| Location       | Mchenry, IL, US                           |
| Contact        | MATHEW MADAPPALLY                         |
| 510(k) history | 164 submissions · 164 cleared · 1984-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k850923/>; 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 May 14, 2026