

**K800902 BUN-COLOR 2, BLOOD UREA NITROGEN TEST**Jun 9, 1980  
52 days to decisionK800902 · Product code: **CDL** · Chemistry  
Source: <https://www.510kdatabase.net/k800902/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Traditional                               |
| Device classification | Berthelot Indophenol, Urea Nitrogen (CDL) |
| Date received         | Apr 18, 1980                              |
| Decision date         | Jun 9, 1980                               |
| Days to decision      | 52 days                                   |
| Third-party review    | No  |

**APPLICANT**

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| Company        | <b>Sclavo, Inc.</b>                     |
| Location       | Mchenry, IL, US                         |
| 510(k) history | 82 submissions · 82 cleared · 1977-1992 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k800902/> 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 29, 2026