

**K852611 TEST UROBILINOGEN IN URINE & LEUKOCYTES IN URINE**Sep 3, 1985  
76 days to decisionK852611 · Product code: **CDM** · Chemistry  
Source: <https://www.510kdatabase.net/k852611/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                              |
| Submission type       | Traditional   |
| Device classification | Diazonium Colorimetry, Urobilinogen (urinary, Non-quant.) (CDM) |
| Date received         | Jun 19, 1985  |
| Decision date         | Sep 3, 1985   |
| Days to decision      | 76 days   |
| Third-party review    | No  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Miles Laboratories, Inc.</b>           |
| Location       | Mchenry, IL, US                           |
| Contact        | JOHN H ENGELMANN                          |
| 510(k) history | 158 submissions · 158 cleared · 1976-1988 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k852611/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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