

K033548 ROCHE DIAGNOSTICS URISYS 1100 URINE ANALYZERNov 24, 2003
12 days to decisionK033548 · Product code: **KHE** · Chemistry
Source: <https://www.510kdatabase.net/k033548/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Reagent, Occult Blood (KHE) |
| Date received | Nov 12, 2003 |
| Decision date | Nov 24, 2003 |
| Days to decision | 12 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Roche Diagnostics Corp. |
| Location | Indianapolis, IN, US |
| Contact | JENNIFER TRIBBETT |
| 510(k) history | 264 submissions · 263 cleared · 1999-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033548/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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