

K113433 SIMPLEXA C. DIFFICILE UNIVERSAL DIRECTApr 4, 2012
135 days to decisionK113433 · Product code: **OMN** · Microbiology
Source: <https://www.510kdatabase.net/k113433/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | C. Difficile Nucleic Acid Amplification Test Assay (OMN) |
| Date received | Nov 21, 2011 |
| Decision date | Apr 4, 2012 |
| Days to decision | 135 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Focus Diagnostics, Inc. |
| Location | Cypress, CA, US |
| Contact | SHARON YOUNG |
| 510(k) history | 14 submissions · 13 cleared · 2007-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113433/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026