

K132235 IMDX C.DIFFICILE FOR ABBOTT M2000Oct 11, 2013
85 days to decisionK132235 · Product code: **OZN** · Microbiology
Source: <https://www.510kdatabase.net/k132235/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | C. Difficile Toxin Gene Amplification Assay (OZN) |
| Date received | Jul 18, 2013 |
| Decision date | Oct 11, 2013 |
| Days to decision | 85 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Intelligent Medical Devices, Inc. |
| Location | Beverly, MA, US |
| Contact | FRAN WHITE |
| 510(k) history | 4 submissions · 4 cleared · 2013-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132235/> 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