

K123197 VERIGENE C. DIFFICILE NUCLEIC ACID TEST (CDF)Dec 5, 2012
55 days to decisionK123197 · Product code: **OZN** · Microbiology
Source: <https://www.510kdatabase.net/k123197/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | C. Difficile Toxin Gene Amplification Assay (OZN) |
| Date received | Oct 11, 2012 |
| Decision date | Dec 5, 2012 |
| Days to decision | 55 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Nanosphere, Inc. |
| Location | Northbrook, IL, US |
| Contact | MARK DEL VECCHIO |
| 510(k) history | 16 submissions · 15 cleared · 2007-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123197/> 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