

K110012 ILLUMIGENE C. DIFFICILE, AND ILLUMIPRO-10Feb 24, 2011
52 days to decisionK110012 · Product code: **OMN** · Microbiology
Source: <https://www.510kdatabase.net/k110012/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | C. Difficile Nucleic Acid Amplification Test Assay (OMN) |
| Date received | Jan 3, 2011 |
| Decision date | Feb 24, 2011 |
| Days to decision | 52 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Meridian Bioscience, Inc. |
| Location | Cincinnati, OH, US |
| Contact | Michelle L Smith |
| Website | https://www.meridianbioscience.com |
| 510(k) history | 38 submissions · 37 cleared · 2003-2025 |

Meridian Bioscience, Inc. is a diagnostic and life science solutions company with a manufacturing facility in Cincinnati, US. The company develops integrated diagnostic products and molecular reagents for clinical and research applications. Meridian has received FDA 510(k) clearances from total submissions since 2003. The company specializes exclusively in Microbiology devices, including molecular detection assays, pathogen identification systems, and diagnostic analyzers. The latest clearance in 2025 reflects continued regulatory activity and product innovation. Recent c...

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