

**K100818 ILLUMIGENE C. DIFFICILE, ILLUMIPRO-10 AND  
ILLUMIGENE C. DIFFICILE EXTERNAL CONTROL KIT, MODELS  
280050, 610172, 279920**Jul 9, 2010  
108 days to decisionK100818 · Product code: **OMN** · Microbiology  
Source: <https://www.510kdatabase.net/k100818/>**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	Mar 23, 2010
Decision date	Jul 9, 2010
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Meridian Bioscience, Inc.</b>
Location	Cincinnati, OH, US
Contact	Michelle L Smith
Website	<a href="https://www.meridianbioscience.com">https://www.meridianbioscience.com</a>
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...