

K190463 Cepheid Xpert C. difficile/Epi Control PanelApr 19, 2019
52 days to decisionK190463 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k190463/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assayed External Control Material For Microbiology Nucleic Acid Amplification (nat) Assays (PMN)
Date received	Feb 26, 2019
Decision date	Apr 19, 2019
Days to decision	52 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Microbiologics, Inc.
Location	St. Cloud, MN, US
Contact	Tina Sobania
510(k) history	18 submissions · 18 cleared · 1995-2019

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