

K190086 Cepheid Xpert Respiratory Control PanelOct 7, 2019
263 days to decisionK190086 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k190086/>**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	Jan 17, 2019
Decision date	Oct 7, 2019
Days to decision	263 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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