

K191172 Cepheid Xpert MRSA NxG Control PanelJun 20, 2019
50 days to decisionK191172 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k191172/>**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	May 1, 2019
Decision date	Jun 20, 2019
Days to decision	50 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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