

K182472 Cepheid Xpert GBS LB Control PanelNov 8, 2018
59 days to decisionK182472 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k182472/>**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	Sep 10, 2018
Decision date	Nov 8, 2018
Days to decision	59 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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