

K190223 Cepheid Xpert CT/NG Control Panel

May 8, 2019
92 days to decision

K190223 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k190223/>

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 5, 2019
Decision date	May 8, 2019
Days to decision	92 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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Device record: <https://www.510kdatabase.net/k190223/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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