

K181683 BD MAX CT/GC/TV 20-Day QC PanelAug 28, 2018
63 days to decisionK181683 · Product code: **PMN** · Microbiology
Source: <https://www.510kdatabase.net/k181683/>**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	Jun 26, 2018
Decision date	Aug 28, 2018
Days to decision	63 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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