

K190613 BD MAX Check-Points CPOAug 29, 2019
171 days to decisionK190613 · Product code: **POC** · Microbiology
Source: <https://www.510kdatabase.net/k190613/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nucleic Acid Amplification Test, Dna, Antimicrobial Resistance Marker, Direct Specimen (POC)
Date received	Mar 11, 2019
Decision date	Aug 29, 2019
Days to decision	171 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Check-Points Health B.V.
Location	Wageningen, NL
Contact	Pieter Vos
510(k) history	1 submissions · 1 cleared · 2019-2019

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