

K193419 MBT SepsityperDec 27, 2020
384 days to decisionK193419 · Product code: **QNJ** · Microbiology
Source: <https://www.510kdatabase.net/k193419/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mass Spectrometry, Microorganism Identification, Blood Culture (QNJ)
Date received	Dec 9, 2019
Decision date	Dec 27, 2020
Days to decision	384 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Bruker Daltonik GmbH
Location	Bremen, DE
Contact	Peter Trinder
510(k) history	3 submissions · 2 cleared · 2017-2020

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