

K251495 MBT Compass HT CA SoftwareAug 13, 2025
90 days to decisionK251495 · Product code: **QBN** · Microbiology
Source: <https://www.510kdatabase.net/k251495/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mass Spectrometry, Maldi Tof, Microorganism Identification, Cultured Isolates (QBN)
Date received	May 15, 2025
Decision date	Aug 13, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MBT FAST Shuttle US IVD

APPLICANT

Company	Bruker Daltonics GmbH & Co. KG
Location	Bremen, DE
Contact	Kirsten Webner
510(k) history	1 submissions · 1 cleared · 2025-2025

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