

K163536 MALDI Biotyper CA (MBT-CA) System, MBT smart CA SystemJul 26, 2017
222 days to decisionK163536 · Product code: **PEX** · Microbiology
Source: <https://www.510kdatabase.net/k163536/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Mass Spectrometry, Maldi Tof, Microorganism Identification, Cultured Isolates (PEX)
Date received	Dec 16, 2016
Decision date	Jul 26, 2017
Days to decision	222 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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