

K130831 MALDI BIOTYPER CA (MBT-CA) SYSTEMNov 21, 2013
240 days to decisionK130831 · Product code: **PEX** · Microbiology
Source: <https://www.510kdatabase.net/k130831/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Mass Spectrometry, Maldi Tof, Microorganism Identification, Cultured Isolates (PEX)
Date received	Mar 26, 2013
Decision date	Nov 21, 2013
Days to decision	240 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bruker Daltonics, Inc.
Location	Beverly, MA, US
Contact	FRAN WHITE
510(k) history	2 submissions · 2 cleared · 2013-2015

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