

K142677 MALDI Biotyper CA System

Mar 27, 2015
189 days to decision

K142677 · Product code: **PEX** · Microbiology
Source: <https://www.510kdatabase.net/k142677/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Mass Spectrometry, Maldi Tof, Microorganism Identification, Cultured Isolates (PEX)
Date received	Sep 19, 2014
Decision date	Mar 27, 2015
Days to decision	189 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k142677/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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