

K954468 MB/BACT MYCROBACTERIA DETECTION SYSTEMJul 22, 1996
300 days to decisionK954468 · Product code: **MDB** · Microbiology
Source: <https://www.510kdatabase.net/k954468/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Blood Culturing (MDB)
Date received	Sep 26, 1995
Decision date	Jul 22, 1996
Days to decision	300 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Organon Teknika Corp.
Location	Mchenry, IL, US
Contact	ANN M QUINN
510(k) history	130 submissions · 129 cleared · 1980-2000

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