

**K000378 BACT/ALERT MB CULTURE BOTTLE**Mar 2, 2000  
24 days to decisionK000378 · Product code: **MDB** · Microbiology  
Source: <https://www.510kdatabase.net/k000378/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Blood Culturing (MDB)
Date received	Feb 7, 2000
Decision date	Mar 2, 2000
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Organon Teknika Corp.</b>
Location	Mchenry, IL, US
Contact	REBECCA A RIVAS
510(k) history	130 submissions · 129 cleared · 1980-2000

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000378/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 22, 2026