

K992400 BACTALERT FASep 3, 1999
46 days to decisionK992400 · Product code: **MDB** · Microbiology
Source: <https://www.510kdatabase.net/k992400/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Blood Culturing (MDB)
Date received	Jul 19, 1999
Decision date	Sep 3, 1999
Days to decision	46 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992400/> Data sourced from FDA 510(k) public records (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. - Generated May 22, 2026