

K033064 MYCOPLASMA IGGNov 26, 2003
58 days to decisionK033064 · Product code: **LON** · Microbiology
Source: <https://www.510kdatabase.net/k033064/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Sep 29, 2003
Decision date	Nov 26, 2003
Days to decision	58 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Trinity Biotech USA
Location	Jamestown, NY, US
Contact	Bonnie B DeJoy
510(k) history	11 submissions · 11 cleared · 1999-2014

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