

**K063365 SYNERGIES PLUS GRAM-POSITIVE MIC/COMBO
 PANELS WITH GENTAMICIN (0.06-32MG/ML LONG DILUTION
 SEQUENCE**

Dec 8, 2006
 31 days to decision

K063365 · Product code: **LON** · Microbiology
 Source: <https://www.510kdatabase.net/k063365/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Automated, Antimicrobial Susceptibility, Short Incubation (LON)
Date received	Nov 7, 2006
Decision date	Dec 8, 2006
Days to decision	31 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dade Behring, Inc.
Location	Newark,, DE, US
Contact	ROBERT EUSEBIO
510(k) history	343 submissions · 343 cleared · 1978-2010

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k063365/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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