

K092407 REMEL SPECTRA MRSA

Oct 8, 2010
428 days to decision

K092407 · Product code: **JSO** · Microbiology
Source: <https://www.510kdatabase.net/k092407/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture Media, Antimicrobial Susceptibility Test, Excluding Mueller Hinton Agar (JSO)
Date received	Aug 6, 2009
Decision date	Oct 8, 2010
Days to decision	428 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Remel, Inc.
Location	Lenexa, KS, US
Contact	MARY ANN SILVIUS
510(k) history	17 submissions · 17 cleared · 1994-2017

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k092407/> 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 June 1, 2026