

K092819 REMEL SPECTRA VREJul 15, 2010
304 days to decisionK092819 · Product code: **JSO** · Microbiology
Source: <https://www.510kdatabase.net/k092819/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Culture Media, Antimicrobial Susceptibility Test, Excluding Mueller Hinton Agar (JSO)
Date received	Sep 14, 2009
Decision date	Jul 15, 2010
Days to decision	304 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Thermo Fisher Scientific
Location	Noble Park, AU
Contact	MARY ANN SILVIUS
Website	http://www.thermofisher.com/
510(k) history	64 submissions · 64 cleared · 2007-2025

Thermo Fisher Scientific is a global life science and clinical research company based in Waltham, Massachusetts. The company operates a facility in Noble Park, Australia, providing scientific consumables, equipment, and services worldwide. Thermo Fisher has received FDA 510(k) clearances from total submissions since 2007. The company specializes primarily in Microbiology devices, which represent 89% of its regulatory submissions. Recent clearances include multiple Sensititre susceptibility systems for antimicrobial testing. The latest FDA 510(k) clearance was granted in 2...