

K252014 The Sensititre 18-24 hour MIC or Breakpoint Susceptibility System with Amikacin in the dilution range of 0.25-256 ug/mL

Aug 28, 2025
62 days to decision

K252014 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k252014/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Jun 27, 2025
Decision date	Aug 28, 2025
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Statement

APPLICANT

Company	Thermo Fisher Scientific
Location	Noble Park, AU
Contact	Joel Mathew
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...