

K152774 The Sensititre 18-24 hour MIC or Breakpoint Susceptibility System with Ceftazidime/Avibactam in the dilutions range of 0.015/4 - 32/4 ug/mL

Dec 21, 2015
87 days to decision

K152774 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k152774/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Sep 25, 2015
Decision date	Dec 21, 2015
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Thermo Fisher Scientific
Location	Noble Park, AU
Contact	CYNTHIA KNAPP
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...