

# K243169 The Sensititre 18-24 hour MIC or Breakpoint Susceptibility System with Ceftobiprole in the dilution range of 0.008-16 ug/mL

Dec 19, 2024  
80 days to decisionK243169 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k243169/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Sep 30, 2024
Decision date	Dec 19, 2024
Days to decision	80 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Thermo Fisher Scientific</b>
Location	Noble Park, AU
Contact	Joel Mathew
Website	<a href="http://www.thermofisher.com/">http://www.thermofisher.com/</a>
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...

---