

## K242905 The Sensititre 20-24 hour Haemophilus influenzae/Streptococcus pneumoniae (HP) MIC or Breakpoint Susceptibility System with Linezolid in the dilution range of 0.12-32 ug/mL

Feb 10, 2025  
139 days to decision

K242905 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k242905/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Sep 24, 2024
Decision date	Feb 10, 2025
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Statement

### APPLICANT

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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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k242905/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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