

K243201 The Sensititre 20-24 hour Haemophilus influenzae/Streptococcus pneumoniae (HP) MIC or Breakpoint Susceptibility System with penicillin in the dilution range of 0.015-32 ug/mL

Feb 10, 2025
132 days to decision

K243201 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k243201/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Oct 1, 2024
Decision date	Feb 10, 2025
Days to decision	132 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...

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Device record: <https://www.510kdatabase.net/k243201/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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