

# K230935 Sensititre 20-24 hour Haemophilus influenzae/Streptococcus pneumoniae MIC, or Breakpoint Susceptibility System with Imipenem-relebactam in the dilution, range of 0.03/4-128-4ug/ml (Haemophilus influenzae)

Jun 30, 2023  
88 days to decision

K230935 · Product code: JWY · Microbiology  
Source: <https://www.510kdatabase.net/k230935/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Apr 3, 2023
Decision date	Jun 30, 2023
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

## APPLICANT

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Company	<b>Thermo Fisher Scientific</b>
Location	Noble Park, AU
Contact	Cynthia Knapp
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/k230935/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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