

K193538 Sensititre 18-24 hour MIC or Breakpoint Susceptibility System with Cefiderocol in the dilution range of 0.03-64 µg/ml

Mar 12, 2020
83 days to decision

K193538 · Product code: JWY · Microbiology
Source: <https://www.510kdatabase.net/k193538/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Dec 20, 2019
Decision date	Mar 12, 2020
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	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...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k193538/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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