CLEARED

Jul 23, 2021
317 days to decision

K202612 Sensititre 20-24 hour Haemophilus influenzae /Streptococcus pneumoniae MIC or Breakpoint Susceptibility System with Dtest (containing erythromycin at 1 ug/mL and clindamycin at 0.5 ug/mL)

K202612 · Product code: **JWY** · Microbiology
Source: https://www.510kdatabase.net/k202612/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Manual Antimicrobial Susceptibility Test Systems (JWY)
Date received	Sep 9, 2020
Decision date	Jul 23, 2021
Days to decision	317 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...