

**K250789 Thermo Scientific Oxoid Aztreonam/Avibactam Disc
(30/20 µg) AZA50**Jun 12, 2025
90 days to decisionK250789 · Product code: JTN · Microbiology
Source: <https://www.510kdatabase.net/k250789/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	Mar 14, 2025
Decision date	Jun 12, 2025
Days to decision	90 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 (Oxoid Ltd.)
Location	Basingstroke, GB
Contact	Sonali Karnik
510(k) history	2 submissions · 2 cleared · 2025-2025

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