

K231806 Thermo Scientific Oxoid Rezafungin Disc (5 µg) RZF5Mar 22, 2024
276 days to decisionK231806 · Product code: JTN · Microbiology
Source: <https://www.510kdatabase.net/k231806/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Susceptibility Test Discs, Antimicrobial (JTN)
Date received	Jun 20, 2023
Decision date	Mar 22, 2024
Days to decision	276 days
Third-party review	No
Combination product	No
PCCP authorized	Yes - Predetermined Change Control Plan (AI/SaMD)
Summary / Statement	Statement

APPLICANT

Company	Oxoid Limited (Part of Thermo Fisher Scientific)
Location	Basingstroke, GB
Contact	Amie Lovatt
510(k) history	7 submissions · 7 cleared · 2018-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k231806/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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