

**K193508 Thermo Scientific Oxoid Eravacycline Disc (20ug)  
ERV20**Dec 4, 2020  
352 days to decisionK193508 · Product code: **JTN** · Microbiology  
Source: <https://www.510kdatabase.net/k193508/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | Susceptibility Test Discs, Antimicrobial (JTN) |
| Date received         | Dec 18, 2019                                   |
| Decision date         | Dec 4, 2020                                    |
| Days to decision      | 352 days                                       |
| Third-party review    | No   |
| Summary / Statement   | Statement                                      |

**APPLICANT**

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|----------------|---|
| Company        | <b>Oxoid Limited (Part of Thermo Fisher Scientific)</b> |
| Location       | Basingstroke, GB  |
| Contact        | Philip Brame  |
| 510(k) history | 7 submissions · 7 cleared · 2018-2024                   |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k193508/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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