

**K251337 Thermo Scientific Oxoid Gepotidacin Disc (10 µg)  
GEP10**Dec 5, 2025  
219 days to decisionK251337 · Product code: **JTN** · Microbiology  
Source: <https://www.510kdatabase.net/k251337/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Susceptibility Test Discs, Antimicrobial (JTN)    |
| Date received         | Apr 30, 2025                                      |
| Decision date         | Dec 5, 2025                                       |
| Days to decision      | 219 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | Yes - Predetermined Change Control Plan (AI/SaMD) |
| Summary / Statement   | Statement   |

**APPLICANT**

---

|                |  |
|----------------|--|
| Company        | <b>Thermo Fisher Scientific (Oxoid Ltd.)</b> |
| Location       | Basingstroke, GB                             |
| Contact        | Sonali Karnik                                |
| 510(k) history | 2 submissions · 2 cleared · 2025-2025        |

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251337/>. Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 14, 2026