

K223844 Sensititre 20-24-hour Haemophilus influenzae/Streptococcus pneumoniae MIC or Breakpoint Susceptibility System with Delafloxacin in the dilution range of 0.00025-8ug/ml (Streptococcus species) and 0.000125-8ug/ml (Haemophilus influenzae)

Mar 21, 2023
89 days to decision

K223844 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k223844/>

SUBMISSION DETAILS

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Manual Antimicrobial Susceptibility Test Systems (JWY) |
| Date received | Dec 22, 2022 |
| Decision date | Mar 21, 2023 |
| Days to decision | 89 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...