

K162854 Liofilchem MIC Test Strip (MTS) Meropenem 0.002-32.0 ug/mlDec 19, 2016
68 days to decisionK162854 · Product code: **JWY** · Microbiology
Source: <https://www.510kdatabase.net/k162854/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Manual Antimicrobial Susceptibility Test Systems (JWY) |
| Date received | Oct 12, 2016 |
| Decision date | Dec 19, 2016 |
| Days to decision | 68 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Liofilchem S. R. L. |
| Location | Abruzzi, IT |
| Contact | Fabio Brocco |
| 510(k) history | 35 submissions · 35 cleared · 2016-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k162854/> Data sourced from FDA 510(k) public records (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. - Generated June 2, 2026