

**K191908 MTS Imipenem 0.016-256 µg/mL**Sep 4, 2019  
50 days to decisionK191908 · Product code: **JWY** · Microbiology  
Source: <https://www.510kdatabase.net/k191908/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Manual Antimicrobial Susceptibility Test Systems (JWY) |
| Date received         | Jul 16, 2019   |
| Decision date         | Sep 4, 2019  |
| Days to decision      | 50 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Statement  |

**APPLICANT**

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

**REGULATORY CONSULTANT**

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|-----------------|-------------------------------------|
| Consulting firm | <b>Laboratory Specialists, Inc.</b> |
| Contact         | Anne R. Windau                      |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191908/> 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 June 28, 2026