FDA 510(k) Premarket Notification

K191908 MTS Imipenem 0.016-256 µg/mL

CLEARED

Sep 4, 2019
50 days to decision

K191908 · Product code: **JWY** · Microbiology
Source: https://www.510kdatabase.net/k191908/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Laboratory Specialists, Inc.**
Contact	Anne R. Windau

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