FDA 510(k) Premarket Notification

K191288 Acuitas AMR Gene Panel

CLEARED

Sep 30, 2021
871 days to decision

K191288 · Product code: **PMY** · Microbiology
Source: https://www.510kdatabase.net/k191288/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Nucleic Acid Amplification Test, Dna, Carbapenem Non-susceptible Gram Negative Organism, Colony (PMY)
Date received	May 13, 2019
Decision date	Sep 30, 2021
Days to decision	871 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Opgen, Inc.**
Location	Rockville, MD, US
Contact	Autumn Collasius
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Randy Prebula

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