FDA 510(k) Premarket Notification

K230675 VITEK REVEAL GN AST Assay and VITEK REVEAL AST System

CLEARED

Jun 20, 2024
468 days to decision

K230675 · Product code: **SAN** · Microbiology
Source: https://www.510kdatabase.net/k230675/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Automated Antimicrobial Susceptibility Test System For Positive Blood Culture Samples (SAN)
Date received	Mar 10, 2023
Decision date	Jun 20, 2024
Days to decision	468 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Specific Diagnostics, LLC**
Location	San Jose, CA, US
Contact	Jolyn Tenllado
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**MDC Associates**
Contact	Katie Hahnemann

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