FDA 510(k) Premarket Notification

CLEARED

K243872 BD Veritor System for SARS-CoV-2

Jun 16, 2025
181 days to decision

K243872 · Product code: **QVF** · Microbiology
Source: https://www.510kdatabase.net/k243872/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Dual Track
Device classification	Simple Point-of-care Device To Directly Detect Sars-cov-2 Viral Targets From Clinical Specimens In Near-patient Settings (QVF)
Date received	Dec 17, 2024
Decision date	Jun 16, 2025
Days to decision	181 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Becton, Dickinson and Company**
Location	Franklin Lakes, NJ, US
Contact	Thi My Lan Dang
Website	https://www.bd.com
510(k) history	134 submissions · 134 cleared · 2010-2026

Becton, Dickinson and Company is an American multinational medical technology company headquartered in Franklin Lakes, New Jersey. BD manufactures and sells medical devices, instrument systems, and reagents globally. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions spanning 2010 to 2026. BD's cleared devices span multiple categories including microbiology systems, blood collection products, and general hospital devices. The company's latest clearance in 2026 reflects continued innovation and regulatory engagemen...