FDA 510(k) Premarket Notification

CLEARED

K244047 Navi™ Needle-free Blood Collection Device (VNC20500FG, VNC22500FG, VNC24500FG)

May 23, 2025
143 days to decision

K244047 · Product code: **JKA** · General Hospital
Source: https://www.510kdatabase.net/k244047/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	Dec 31, 2024
Decision date	May 23, 2025
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Venocare, Inc.**
Location	Doral, FL, US
Contact	Raul Leyte-Vidal
510(k) history	2 submissions · 2 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	**Daniel & Daniel, LLC**
Contact	Mark Smutka

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