FDA 510(k) Premarket Notification

CLEARED

K201237 Velano Vascular Blood Collection Adapter

Oct 3, 2022
879 days to decision

K201237 · Product code: **JKA** · General Hospital
Source: https://www.510kdatabase.net/k201237/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	May 7, 2020
Decision date	Oct 3, 2022
Days to decision	879 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Velano Vascular**
Location	Philadelphia, PA, US
Contact	Tiffini Wittwer
510(k) history	7 submissions · 7 cleared · 2016-2022

REGULATORY CONSULTANT

Consulting firm	**Velano Vascular**
Contact	Tiffini Wittwer

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