FDA 510(k) Premarket Notification

K230865 PIVO™ Pro Needle-free Blood Collection Device

CLEARED

Sep 28, 2023
183 days to decision

K230865 · Product code: **JKA** · General Hospital
Source: https://www.510kdatabase.net/k230865/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	Mar 29, 2023
Decision date	Sep 28, 2023
Days to decision	183 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Becton Dickinson Infusion Therapy Systems, Inc.**
Location	Sandy, UT, US
Contact	Amy Moore
510(k) history	36 submissions · 36 cleared · 1997-2026