FDA 510(k) Premarket Notification

CLEARED

K220258 20G Open-System Ally Device Kit (AV100000), 22G Open-System Ally Device Kit (AV110000)

Jul 14, 2022
164 days to decision

K220258 · Product code: **JKA** · General Hospital
Source: https://www.510kdatabase.net/k220258/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Vials, Systems, Serum Separators, Blood Collection (JKA)
Date received	Jan 31, 2022
Decision date	Jul 14, 2022
Days to decision	164 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Avia Vascular**
Location	Salt Lake City, UT, US
Contact	Kevin Cook
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	**Medventure Health**
Contact	Jonathan Holmes

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k220258/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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