FDA 510(k) Premarket Notification

K220114 PowerPAK Syringe

CLEARED

Jan 25, 2023
376 days to decision

K220114 · Product code: **MEG** · General Hospital
Source: https://www.510kdatabase.net/k220114/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Antistick (MEG)
Date received	Jan 14, 2022
Decision date	Jan 25, 2023
Days to decision	376 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Vault Paragon Group, Inc.**
Location	Oakland, CA, US
Contact	Sari Luciano
510(k) history	2 submissions · 2 cleared · 2023-2025