FDA 510(k) Premarket Notification

K230698 Anivia SG1000 Pump Console

CLEARED

Apr 18, 2023
36 days to decision

K230698 · Product code: **DWA** · Cardiovascular
Source: https://www.510kdatabase.net/k230698/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	Mar 13, 2023
Decision date	Apr 18, 2023
Days to decision	36 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Apmtd, Inc.**
Location	Wilmington, MA, US
Contact	John Sasso
510(k) history	2 submissions · 2 cleared · 2023-2023