FDA 510(k) Premarket Notification

# K221491 Anivia SG1000 Pump Console

**CLEARED**

Feb 3, 2023
256 days to decision

K221491 · Product code: **DWA** · Cardiovascular
Source: https://www.510kdatabase.net/k221491/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Control, Pump Speed, Cardiopulmonary Bypass (DWA) |
| Date received | May 23, 2022 |
| Decision date | Feb 3, 2023 |
| Days to decision | 256 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 |