

**K221491 Anivia SG1000 Pump Console**Feb 3, 2023  
256 days to decisionK221491 · Product code: **DWA** · CardiovascularSource: <https://www.510kdatabase.net/k221491/>**SUBMISSION DETAILS**

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|-----------------------|---|
| 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**

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|----------------|---------------------------------------|
| Company        | <b>ApmtD, Inc.</b>                    |
| Location       | Wilmington, MA, US                    |
| Contact        | John Sasso                            |
| 510(k) history | 2 submissions · 2 cleared · 2023-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221491/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026