

**K223050 AZUR HydroPack 18 (45-880005)**Dec 21, 2022  
83 days to decisionK223050 · Product code: **KRD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k223050/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                     |
| Submission type       | Traditional  |
| Device classification | Device, Vascular, For Promoting Embolization (KRD)     |
| Date received         | Sep 29, 2022   |
| Decision date         | Dec 21, 2022   |
| Days to decision      | 83 days  |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |
| Other names           | 45-880010; 45-880020; 45-880035; 45-880050; 45-880060) |

**APPLICANT**

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|----------------|---|
| Company        | <b>MicroVention, Inc.</b>               |
| Location       | Aliso Viejo, CA, US                     |
| Contact        | Riddhi Pandya                           |
| 510(k) history | 85 submissions · 85 cleared · 2001-2024 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k223050/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 14, 2026