

**K200612 R501 aortic root cannula without vent line, R502 aortic root cannula with vent line**Nov 17, 2020  
253 days to decisionK200612 · Product code: **DWF** · Cardiovascular  
Source: <https://www.510kdatabase.net/k200612/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                                   |
| Submission type       | Traditional  |
| Device classification | Catheter, Cannula And Tubing, Vascular, Cardiopulmonary Bypass (DWF) |
| Date received         | Mar 9, 2020  |
| Decision date         | Nov 17, 2020   |
| Days to decision      | 253 days   |
| Third-party review    | No   |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Sorin Group Italia S.R.L.</b>        |
| Location       | Mirandola, IT                           |
| Contact        | Luigi Vecchi                            |
| 510(k) history | 61 submissions · 61 cleared · 1995-2026 |

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k200612/> 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 June 28, 2026