

**K241236 XTRA Collection sets**Aug 16, 2024  
106 days to decisionK241236 · Product code: **CAC** · Cardiovascular  
Source: <https://www.510kdatabase.net/k241236/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Apparatus, Autotransfusion (CAC)   |
| Date received         | May 2, 2024                        |
| Decision date         | Aug 16, 2024                       |
| Days to decision      | 106 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |
| Other names           | XTRA Sequestration set X           |

**APPLICANT**

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|----------------|---|
| Company        | <b>Sorin Group Italia S.R.L.</b>        |
| Location       | Mirandola, IT                           |
| Contact        | Martina Carlini                         |
| 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/k241236/> 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 13, 2026