

K242953 KIDS Arterial FiltersDec 20, 2024
86 days to decisionK242953 · Product code: **DTM** · CardiovascularSource: <https://www.510kdatabase.net/k242953/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Filter, Blood, Cardiopulmonary Bypass, Arterial Line (DTM) |
| Date received | Sep 25, 2024 |
| Decision date | Dec 20, 2024 |
| Days to decision | 86 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Sorin Group Italia S.R.L. |
| Location | Mirandola, IT |
| Contact | Martina Carlini |
| 510(k) history | 61 submissions · 61 cleared · 1995-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242953/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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