

K240584 XTRA Autotransfusion System (with XTRA Bowl sets)Apr 29, 2024
59 days to decisionK240584 · Product code: **CAC** · Cardiovascular
Source: <https://www.510kdatabase.net/k240584/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Apparatus, Autotransfusion (CAC)
Date received	Mar 1, 2024
Decision date	Apr 29, 2024
Days to decision	59 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	Luigi Vecchi
510(k) history	61 submissions · 61 cleared · 1995-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240584/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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