

**K092895 APEX HP M ADULT HOLLOW FIBER MEMBRANE
OXYGENATOR**Oct 19, 2009
28 days to decisionK092895 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k092895/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Sep 21, 2009
Decision date	Oct 19, 2009
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092895/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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