

**K083021 APEX HP M PH.I.S.I.O. ADULT HOLLOW FIBER
MEMBRANE OXYGENATOR**Oct 29, 2008
20 days to decisionK083021 · Product code: DTZ · Cardiovascular
Source: <https://www.510kdatabase.net/k083021/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Oct 9, 2008
Decision date	Oct 29, 2008
Days to decision	20 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/k083021/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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