FDA 510(k) Premarket Notification

K092895 APEX HP M ADULT HOLLOW FIBER MEMBRANE OXYGENATOR

CLEARED

Oct 19, 2009
28 days to decision

K092895 · 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