FDA 510(k) Premarket Notification

CLEARED

K083021 APEX HP M PH.I.S.I.O. ADULT HOLLOW FIBER MEMBRANE OXYGENATOR

Oct 29, 2008
20 days to decision

K083021 · 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