FDA 510(k) Premarket Notification

K020351 D 903 AVANT 2 PH.I.S.I.O. ADULT HOLLOW FIBER OXYGENATOR

CLEARED

Feb 26, 2002
22 days to decision

K020351 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k020351/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 4, 2002
Decision date	Feb 26, 2002
Days to decision	22 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dideco S.P.A.**
Location	Waltham, MA, US
Contact	BARRY SALL
510(k) history	22 submissions · 22 cleared · 1997-2004