FDA 510(k) Premarket Notification

K020997 APEX PH.I.S.I.O. ADULT HOLLOW FIBER MEMBRANE OXYGENATOR

CLEARED

Apr 4, 2002
7 days to decision

K020997 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k020997/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 28, 2002
Decision date	Apr 4, 2002
Days to decision	7 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