FDA 510(k) Premarket Notification

CLEARED

K050447 PERFORMA ADULT HOLLOW FIBER MEMBRANE OXYGENATOR

Mar 8, 2005
14 days to decision

K050447 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k050447/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Feb 22, 2005
Decision date	Mar 8, 2005
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Dideco S.R.L.**
Location	Waltham, MA, US
Contact	BARRY SALL
510(k) history	6 submissions · 6 cleared · 1996-2005