FDA 510(k) Premarket Notification

K113148 E-PASS

CLEARED

Feb 28, 2012
127 days to decision

K113148 · Product code: **DTL** · Cardiovascular
Source: https://www.510kdatabase.net/k113148/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (DTL)
Date received	Oct 24, 2011
Decision date	Feb 28, 2012
Days to decision	127 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Synexmed(Shenzhen)Company Limited**
Location	Shenzhen, CN
Contact	TONY ZHANG
510(k) history	2 submissions · 2 cleared · 2012-2012