

**K113148 E-PASS**Feb 28, 2012  
127 days to decisionK113148 · Product code: **DTL** · Cardiovascular  
Source: <https://www.510kdatabase.net/k113148/>**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k113148/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 15, 2026