

**K151936 Steerable Intracardiac Catheter Introducer Kit and Transseptal Needle**Dec 4, 2015  
143 days to decisionK151936 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k151936/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 14, 2015
Decision date	Dec 4, 2015
Days to decision	143 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Synaptic Medical Limited</b>
Location	Shanghai, CN
Contact	Yang Tiecheng
510(k) history	3 submissions · 2 cleared · 2014-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k151936/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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