

**K132943 INTRACARDIC CATHETER INTRODUCER KIT AND
TRANSEPTAL NEEDLE**Aug 29, 2014
344 days to decisionK132943 · Product code: **DRC** · Cardiovascular
Source: <https://www.510kdatabase.net/k132943/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Trocar (DRC)
Date received	Sep 19, 2013
Decision date	Aug 29, 2014
Days to decision	344 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Synaptic Medical Limited
Location	Shanghai, CN
Contact	Diana Hong
510(k) history	3 submissions · 2 cleared · 2014-2015

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k132943/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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